06-0820-ag(L)

06-1895-ag (CON), 06-2149-ag (CON), 06-2360-ag (CON)

In the U.S. Court of Appeals for the Second Circuit

Natural Resources Defense Council, Inc., Pesticide Action Network North America, Pineros y Campesinos Unidos Del Noroeste, Physicians for Social Responsibility-San Francisco, Farm Labor Organizing Committee, AFL-CIO, and Migrant Clinicians Network,
Petitioners,
v.

United States Environmental Protection Agency,
Respondent.

On Petition for Review of an Order of the
United States Environmental Protection Agency

PETITIONERS' BRIEF

JAN HASSELMAN
PATTI GOLDMAN
Earthjustice
705 Second Avenue, Ste. 203
Seattle, WA 98104
Tel: (206) 343-7340

SHELLEY DAVIS
Farmworker Justice Fund
1010 Vermont Ave., NW, Ste. 915
Washington, DC 20005
Tel: (202) 783-2628

MICHAEL E. WALL
AARON COLANGELO
Natural Resources Defense Council
111 Sutter Street, 20th Floor
San Francisco, CA 94104
Tel: (415) 875-6100

Counsel for Petitioners

TABLE OF CONTENTS

TABLE OF AUTHORITIES

Federal Cases: **Page:**

Federal Statutes, Regulations, and Legislative History:

CORPORATE DISCLOSURE PURSUANT TO RULE 26.1

Petitioners Natural Resources Defense Council, Pesticide Action Network North America, Pineros y Campesinos Unidos del Noroeste, Physicians for Social Responsibility – San Francisco, Farm Labor Organizing Committee, AFL-CIO, and Migrant Clinicians Network have no parent companies, subsidiaries, or affiliates that have issued shares to the public in the United States or abroad.

JURISDICTION

1. Rule 28(a)(4) Jurisdictional Statement. These consolidated petitions for review challenge the Environmental Protection Agency's ("EPA's") final Human Testing Rule, published on February 6, 2006. 71 Fed. Reg. 6138 (Feb. 6, 2006). The Rule cites six statutory sources of authority: section 201 of the Department of the Interior, Environment, and Related Agencies Appropriations Act, 2006, Pub. L. No. 109–54, § 201, 119 Stat. 499, 532; sections 3(a) & 25(a) of the Federal Insecticide, Fungicide, and Rodenticide Act, 7 U.S.C. §§ 136a(a) & 136w(a); section 408(e)(1)(C) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 346a(e)(1)(C); 5 U.S.C. § 301; and 42 U.S.C. § 300v-1(b). The Courts of Appeals have original subject matter jurisdiction over petitions for review of the Rule under 21 U.S.C. § 346a(h)(1).

Petitioner Natural Resources Defense Council filed a petition for review on February 23, 2006. Petitioners Pesticide Action Network North America, Pineros y Campesinos Unidos del Noroeste, and Physicians for Social Responsibility – San Francisco filed a petition for review on February 24, 2006. Petitioners Farm Labor Organizing Committee, AFL-CIO, and Migrant Clinicians Network filed petitions for review on April 7, 2006. These petitions were timely filed, *see* 21 U.S.C. § 346a(h)(1), and consolidated in this Court pursuant to 28 U.S.C. §§ 2112(a)(3) & (5) and an order of the Judicial Panel on Multidistrict Litigation.

2. **Article III Standing.** Petitioners have standing to challenge EPA's rule on behalf of themselves and their members, as more fully set forth in Petitioners' Response to EPA's Motion to Dismiss (Aug. 3, 2006). EPA's Human Testing Rule has led EPA unlawfully to rely on scientifically and ethically flawed human toxicity experiments to relax human health protections for pesticides. Petitioners' members are farmworkers, farmers, medical professionals, and consumers of pesticide-contaminated foods, who are exposed to these dangerous pesticides on the job, in their homes, and on their dinner tables. *See* Decls. of Adam M. Finkel, Sc.D.; Harjinder S. Gill; Beth Koh; Karen Mountain; Stacey Justus Nordgren; Ramon Ramirez; Margaret Reeves, Ph.D.; Rhonda Roff; Gina Solomon, M.D.. M.P.H.; Gina Trujillo; and Baldemar Velasquez (all filed Aug. 3, 2006). Because EPA has and will rely on the Rule to raise pesticide exposure limits for pesticides to which Petitioners' members are exposed, an order vacating the Rule would redress Petitioners' injuries.

The increase in pesticide exposures and uncertainty about such exposure that Petitioners' members face due to the Human Testing Rule are precisely the sorts of harm that this Court has repeatedly recognized as satisfying Article III. *See New York Pub. Interest Research Group v. Whitman*, 321 F.3d 316, 325 (2d Cir. 2003); *Baur v. Veneman*, 352 F.3d 625, 628, 633-34 (2d Cir. 2003); *LaFleur v. Whitman*, 300 F.3d 256, 270 (2d Cir. 2002); *Friends of the Earth, Inc. v. Laidlaw Envtl.*

Servs., 528 U.S. 167, 180-84 (2000); *cf. Bennett v. Spear*, 520 U.S. 154, 168-69 (1997) (admonishing courts not to "wrongly equate[] injury fairly traceable to the defendant with injury as to which the defendant's actions are the very last step in the chain of causation"). Petitioners have standing both to represent their members who face increased pesticide exposure, *see Hunt v. Washington State Apple Comm'n*, 432 U.S. 333, 343 (1977), and to protect their own institutional interests, *see Havens Realty Corp. v. Coleman*, 455 U.S. 363, 379 (1982), in avoiding the economic costs of responding to poisoning incidents affecting their members, *see, e.g.*, Ramirez Decl. ¶¶ 2, 7, 9, 11, 12, 14; Velasquez Decl. ¶¶ 8, 13; Mountain Decl. ¶¶ 4-5, 8, 11-13.

STATEMENT PURUSANT TO LOCAL RULE 28.2

This case arises on petition for review of a final rule of the U.S. Environmental Protection Agency. Administrator Stephen L. Johnson signed the rule. It was published at 71 Fed. Reg. 6138 (Feb. 6, 2006).

ISSUES PRESENTED FOR REVIEW

Whether the Human Testing Rule violates section 201 of the Department of the Interior, Environment, and Related Agencies Appropriations Act, 2006 ("Section 201"), Pub. L. No. 109–54, § 201, 119 Stat. 499, 532, and section 10 of the Administrative Procedure Act, 5 U.S.C. § 706(2)(A), by:

1. failing to prohibit all intentional human dosing pesticide toxicity experiments on pregnant women and children;
2. failing to ensure consistency with the principles proposed by the National Academy of Sciences, including the Academy's proposals that intentional human dosing studies meet rigorous scientific standards, not pose risks to human subjects absent overriding health or environmental benefits, and comport with ethical standards prevailing when the studies were conducted; and
3. failing to ensure consistency with the Nuremberg Code – as well as section 12(a)(2)(P) of the Federal Insecticide, Fungicide, and Rodenticide Act, 7 U.S.C. § 136j(a)(2)(P) – by, *inter alia*, allowing experimentation on humans who have not themselves given free and fully informed consent to the experimentation and without any showing of scientific necessity.

INTRODUCTION

Petitioners challenge EPA's Human Testing Rule. 71 Fed. Reg. 6138 (Feb. 6, 2006). This Rule authorizes and sets standards both for the conduct of experiments in which humans are intentionally dosed with pesticides to assess the chemicals' toxicity and for EPA's use of such studies to establish human health protections. In these experiments, pesticide manufacturers have paid human subjects to eat or drink pesticides, to enter pesticide vapor "chambers," and to have pesticides sprayed into their eyes or rubbed onto their skin. A680-84, 692-93.[1] Pesticide manufacturers have sponsored these experiments to try to develop evidence to weaken public health protections and thereby increase product sales. *See* A126, 146, 155, 334, 440, 496, 671. Unfortunately, the design of many of these experiments has rendered them not only ethically troubling, but statistically incapable of reliably detecting toxic effects that may occur. A60-62. EPA has nevertheless relied on such studies to increase exposure limits for pesticides.[2]

After the National Academy of Sciences ("NAS" or "Academy") in 2004 issued a report critical of EPA's existing practice with respect to such experiments,

---

[1] References are cited to the Appendix as "A[page number]," to the Special Appendix as "SPA[page number]," and to documents in the Administrative Record as "AR[EPA docket number]."

[2] *See, e.g.,* Decl. of Gina Solomon, M.D., M.P.H. (Aug. 3, 2006), ¶¶ 11, 21-22, 39-40 (submitted in support of Petitioners' standing); Decl. of Adam M. Finkel, Sc.D (Aug. 3, 2006), ¶¶ 37-38 (submitted in support of Petitioners' standing); Decl. of Beth Koh (Aug. 3, 2006), Exs. H & J (submitted in support of Petitioners' standing).

see, e,g., A107, 189-90, Congress imposed a moratorium on EPA's use of intentional human dosing toxicity studies for pesticides until EPA promulgated a rule that met congressionally mandated scientific and ethical standards. Specifically, section 201 of EPA's fiscal year 2006 appropriations act directed EPA to promulgate a rule that "shall not permit the use of pregnant women, infants or children as subjects"; "shall be consistent with the principles proposed in the 2004 report of the National Academy of Sciences"; and "shall be consistent with . . . the principles of the Nuremberg Code," a statement of experimental ethics under which Nazi doctors were prosecuted for crimes against humanity following World War II. SPA1, A533-43.

EPA's Human Testing Rule violates each of these statutory commands. Contrary to Section 201's plain language and legislative history, EPA's Rule bars only a subset of intentional dosing pesticide toxicity experiments on pregnant women and children; ignores many of the National Academy's proposed principles; and deviates willfully from the Nuremberg Code's most basic principles. In short, EPA has read Section 201 into oblivion. EPA may not so lightly disregard Congress' command. Because the Human Testing Rule violates Section 201, it should now be set aside.

STATEMENT OF THE CASE

I. EPA Regulation of Pesticides

Pesticides must be "registered" by EPA to be lawfully sold in this country. *See* 7 U.S.C. § 136a. The Federal Insecticide, Fungicide, and Rodenticide Act ("FIFRA"), 7 U.S.C. §§ 136 *et seq.*, authorizes EPA to register a pesticide only if the chemical will perform its intended function without causing any "unreasonable adverse effects on the environment." 7 U.S.C. § 136a(c)(5)(C). This is defined as "any unreasonable risk to man or the environment, taking into account the economic, social, and environmental costs and benefits of the use of any pesticide." 7 U.S.C. § 136(bb).

The Federal Food, Drug, and Cosmetic Act ("FFDCA"), in turn, generally prohibits the sale of food that contains pesticide residue in excess of an EPA-determined "tolerance." *See* 21 U.S.C. §§ 331(a), 342(a)(2)(B), 346(a)(1) & (2). Section 408 of the FFDCA, 21 U.S.C. § 346a, authorizes EPA to establish or leave in effect a tolerance for a pesticide only if EPA determines that the tolerance is "safe." 21 U.S.C. § 346a(b)(2)(A)(i).

In 1996, Congress substantially amended both FIFRA and the FFDCA to provide greater human health protections for pesticides. *See* Food Quality Protection Act of 1996 ("FQPA"), Pub. L. No. 104-170, 110 Stat. 1489 (1996). As amended by the FQPA, section 408 of the FFDCA bars EPA from finding that a

tolerance is "safe" unless "there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue," including "all anticipated dietary exposures and all other exposures for which there is reliable information." 21 U.S.C. § 346a(b)(2)(A)(ii); *accord* 21 U.S.C. § 346a(b)(2)(C)(ii). The FQPA directs EPA to reevaluate the safety of numerous older pesticides under the new standards by specified dates. *See* 21 U.S.C. § 346a(q); 7 U.S.C. § 136a-1(g).

EPA also regulates human exposure to pesticides under an array of other authorities. A147-49. For example, the Safe Drinking Water Act ("SDWA"), 42 U.S.C. § 300g *et seq.*, requires EPA to establish allowable concentrations of contaminants, including pesticides, in drinking water. *See* 40 C.F.R. § 141.61(c). EPA does this by setting "maximum contaminant level goals" ("MCLGs"), *see* 42 U.S.C. § 300g-1(b)(4)(A)) and "maximum contaminant levels" ("MCLs"), *see* 42 U.S.C. §§ 300g-1(b)(3)(C)(i) & (4)(B), both of which explicitly require consideration of risks posed by the contaminants to human health, *see, e.g.*, 42 U.S.C. § 300g-1(b)(1)(A)(i). Similarly, the Comprehensive Environmental Response, Compensation, and Liability Act ("CERCLA"), 42 U.S.C. § 9601 *et seq.*, restricts the release of hazardous substances, including numerous pesticides, *see* 40 C.F.R. § 302.4, to the environment. *See, e.g.*, 42 U.S.C. § 9604, 9606; *see also United States v. Tropical Fruit, S.E.*, 96 F. Supp. 2d 71, 84-91 (D.P.R. 2000).

EPA likewise regulates environmental exposure to pesticides under the Clean Water Act, *see, e.g.*, *Headwaters, Inc. v. Talent Irrigation Dist.*, 243 F.3d 526, 531-32 (9th Cir. 2001),[3] and the Resource Conservation and Recovery Act ("RCRA"), 42 U.S.C. § 6922-6924, which provides for comprehensive controls on hazardous wastes, including waste pesticides, *see* 40 C.F.R. § 261.33 (listing many pesticides regulated under RCRA).

Each of these and similar statutes requires EPA to consider human health risks from toxic exposure. EPA normally conducts such human health risk assessments by applying a traditional framework, A149-53, under which the Agency: (1) reviews toxicological studies to identify harmful effects that the pesticide may have; (2) sets a "reference dose," or "RfD," which is the dose EPA considers "safe"; (3) estimates potential human exposure to the pesticide; and (4) determines whether people will be exposed to unsafe levels of pesticide residue. A151-52. EPA generally determines the reference dose (step 2) by calculating a "no observed adverse effect level" ("NOAEL") from toxicological studies on animals. A153. EPA then calculates a margin of safety to account for scientific unknowns by applying at least two "uncertainty factors." A153. First, because laboratory animals may have lesser sensitivities than humans, EPA typically

[3] *See also* EPA, "2002 Section 303(d) List Fact Sheet for NEW YORK," *available at* http://oaspub.epa.gov/tmdl/waters_list.impairments?state=NY&p_impid=3 (visited May 10, 2006) (listing dozens of New York waterways as "impaired" by pesticide pollution under the Clean Water Act).

reduces the animal NOAEL by an *inter*species uncertainty factor of ten. A153, 269. Second, because individuals within the human population have a wide range of chemical sensitivities, EPA divides the NOAEL by a second, *intra*species uncertainty factor, traditionally also ten. *Id.* EPA's use of both uncertainty factors has been approved by the National Academy of Sciences. A149-150.

In 1993, the National Academy of Sciences recommended that EPA adopt yet a third uncertainty factor to account for the special vulnerabilities of fetuses and young children, including a concern that "the developing organ systems in infants and children (e.g., nervous, endocrine, immune) might be particularly susceptible to pesticides." A154. In the FQPA, Congress responded to the National Academy's recommendation by directing EPA presumptively to use "an additional tenfold margin of safety for the pesticide chemical residue and other sources of exposure . . . for infants and children." 21 U.S.C. § 346a(b)(2)(C). Congress required this additional presumptive uncertainty factor to account for children's relatively greater exposure to pesticides; children's heightened vulnerability to pesticides; and the lack of complete data about both childhood exposure and childhood vulnerability. *Id.*; *see also* A154. EPA is supposed to use the resulting "reference dose" to set pesticide tolerances for foods and, "taking into account the economic, social, and environmental costs and benefits of the use of

any pesticide," 7 U.S.C. § 136(bb), to make pesticide reregistration decisions as well.

II. Factual Background

A. Intentional Dosing Toxicity Studies on Humans

The EPA rulemaking at issue in this litigation, as well as the legislation that mandated that rulemaking, took place against an historical backdrop of experiments in which some researchers have dosed human beings with toxic chemicals and disease agents to determine the subjects' susceptibility.[4] A126, 170-72. Perhaps the most notorious human toxicity experiments were conducted by Nazi doctors during World War II. A536-40 (*United States v. Karl Brandt*, quoted in *The Nazi Doctors & the Nuremberg Code: Human Rights in Human Experimentation* 94, 97-101 (George J. Annas & Michael A. Grodin eds., 1992) ("*The Nazi Doctors*")); A558 (Michael A. Grodin, *Historical Origins of the Nuremberg Code* ("*Historical Origins*"), in *The Nazi Doctors*, at 132). The Nazi doctors were ultimately charged with war crimes and crimes against humanity for, among other things, intentionally infecting prisoners with malaria to test the relative efficacy of drugs and secretly dosing inmates' food with poisons to investigate those chemicals' effects. A536-39. These experiments – and the Nazi

[4] Intentional human tests are experiments in which humans are exposed to chemicals to which they would not otherwise be exposed, as opposed to observational or epidemiological studies, in which data is collected on human exposures that would occur anyway. SPA35 (definitions).

doctors' subsequent prosecution for war crimes and crimes against humanity – ultimately led to the promulgation of the Nuremberg Code, a bedrock declaration of ethical principles for experiments on humans, discussed *infra*, at 15, 49-58.

Toxicity experiments on humans have surfaced in the United States, as well. A418-19. In 1964, American newspapers reported on a study funded by the National Institute of Health in which investigators injected cancerous cells into elderly patients at a hospital in New York. A171. In 1966, a study was reported in which children admitted to New York's Willowbrook State School for the Retarded were injected with a strain of hepatitis. *Id.* Then, in 1972, the *New York Times* uncovered the Tuskegee Syphilis Study, a long-running investigation sponsored by the federal government's Public Health Service in which researchers tried to trace the progress of syphilis by withholding medicines from poor African-American men. A172.

More recently, pesticide manufacturers have submitted to EPA dozens of intentional human dosing toxicity studies involving pesticides. SPA7, A156. As explained in the National Academy of Sciences' exhaustive 2004 report on this issue:

> [S]oon after enactment of the FQPA, companies began submitting to EPA studies in humans that were intended to demonstrate that for certain chemicals the 10-fold interspecies uncertainty factor could be reduced or eliminated. If the studies and the reasoning behind them were accepted by EPA, they could have the effect of at least partially offsetting the FQPA's

> new safety factor for children . . . and increasing the likelihood that existing tolerances, and thus markets, for the pesticides would be maintained.

A156; *see also* SPA27 (71 Fed. Reg. 6161 ("Much third-party research is conducted by private, for profit organizations in the hope that the results will lead to financial benefits, often through changes in government regulation.")).

The National Academy found that some of these studies "involve[d] doses capable of eliciting a biological effect that is . . . potentially adverse in its own right." A155. In a 1992 study, for example, three dozen human subjects were given the pesticide aldicarb – a suspected endocrine, reproductive, and neurological toxin that the European Union has banned – with orange juice at breakfast. A681. The subjects were given doses sufficient to cause a seventy percent drop in their level of cholinesterase, a substance that naturally regulates nervous system function, even though a twenty percent drop represents "a clear toxicological effect" and a fifty percent drop may require treatment with an antidote. A681-82. Similarly, in a 1976 study, carbofuran was given to humans in an attempt to establish "the minimum dose necessary to induce toxic effects (e.g. headache, nausea, and vomiting) in normal male volunteers." *Id.* (internal quotation marks omitted). As recently as 1998, researchers working for Bayer Corporation administered the pesticide azinphos-methyl to humans at a level twice that at which no adverse effects might be expected based on earlier studies. A682.

Many of these studies have suffered from scientific, as well as ethical, weaknesses. For example, these experiments often are conducted on such a narrow sample group that the tests are statistically incapable of reliably detecting adverse effects that would occur across a larger population. As EPA's science advisors explained in a 2001 report, with the small sample in many of these studies:

> It is as if there were 4 black balls representing a toxic effect and 96 white balls representing no toxic effect placed in a jar. Asserting that no toxicity was seen in a study of 50 [human] subjects is no different that [*sic*] reaching into the jar, pulling out a white ball, and stating that only white balls were in the jar.

A60-61.

B. The Development of Standards for Human Research

The first internationally recognized principles governing human experimentation were articulated as part of the final judgment in the military trial of Nazi doctors at Nuremberg, Germany, after World War II. A380, 536-43, 547-558, 566, 1275. The ten principles now known as the "Nuremberg Code" establish, among other things, that "[t]he voluntary consent of the human subject is absolutely essential"; that human experiments may be conducted only if the study will provide results that are both "necessary" and "unprocurable by other methods or means"; and that human experiments must be "so designed and based on the results of animal experimentation . . . that the anticipated results will justify the performance of the experiment." A541-42.

Two decades after the Nuremberg trials, medical ethicist Henry K. Beecher published a sweeping indictment of experiments on humans conducted in this country. A171. Dr. Beecher's investigation, as well as subsequent revelations about the Tuskegee Syphilis Study and similar research, ultimately sparked a long line of regulatory agencies, governmental commissions, and professional societies to develop their own human experimentation codes. In 1964, the World Medical Association ("WMA") issued its "Declaration of Helsinki," which sets forth thirty-two "principles" for medical research involving human subjects. A1283. In 1974, the Department of Health, Education and Welfare issued a rule, regulating federally sponsored research on humans, which ultimately evolved into what is now known as the "Common Rule." A172-73. In 1979, the National Commission for Protection of Human Subjects of Biomedical and Behavioral Research issued a document known as the "Belmont Report" that identified as "basic ethical principles" the concepts of "respect for persons," "beneficence," and "justice." A1289. In 1981, a separate Presidential Commission proposed that all federal agencies adopt the "Common Rule." A173.

EPA adopted subpart A of the "Common Rule" in 1991. A176; SPA12. This Subpart requires both "informed consent" and prior approval by an Institutional Review Board ("IRB") of any human research conducted or funded by EPA. *See* 40 C.F.R. §§ 26.109, 26.111, 26.116; *see generally* SPA10-11 (EPA's

summary of Common Rule requirements). EPA has never adopted the Common Rule's Subparts B, C, or D, which provide additional protections for fetuses and pregnant women; prisoners; and children. A176, 234; *compare* 45 C.F.R. part 46 (HHS Common Rule) *with* 40 C.F.R. §§ 26.101-26.124 (EPA codification of Subpart A of HHS rule). Prior to adoption of the Human Testing Rule at issue here, EPA also lacked any rules governing the third-party human dosing research that EPA uses under its various regulatory programs.

C. The National Academy of Sciences' 2004 Report and Congress' Enactment of Section 201

In December 2001, reacting to rising tide of public controversy over human toxicity studies, A74, EPA asked the National Academy of Sciences to "provide recommendations to the Agency to help address the scientific and ethical questions related to . . . research involving deliberate exposure of human subjects to toxicants when used to identify or quantify toxic endpoints."[5] A68. The National Academy published its 208-page report, *Intentional Human Dosing Studies for EPA Regulatory Purposes: Scientific and Ethical Issues* (the "NAS Report" or "Report"), in 2004. A107.

---

[5] EPA simultaneously announced a temporary moratorium on its use of human tests submitted by third parties. A127. That moratorium was ultimately vacated, for violations of Administrative Procedure Act notice-and-comment requirement, by the District of Columbia Circuit. *See CropLife Am. v. EPA*, 329 F.3d 876, 880-81 (D.C. Cir. 2003).

The Academy's Report set out to address "the vexing question of whether and, if so, under what circumstances EPA should accept and consider intentional human dosing studies conducted by companies or other sources outside the agency . . . to gather evidence relating to the risks of a chemical . . . ." A124. After an extensive review, the Academy concluded that the standards of existing statements of ethical principles were both too "general" and also too "unclear, indeterminate, inconsistent, and even contradictory" to ensure that intentional human dosing experiments for EPA regulatory purposes would be ethical and scientifically valid. A235. The Academy also concluded that, to ensure such experiments were conducted and used in a scientifically valid manner, EPA must "introduce much greater scientific care and rigor into its process." A189.

At the conclusion of its investigation, the Academy set out seventeen specific proposed principles for reform, which the Report enumerates as "Recommendations." For example, the Academy proposed that human toxicity studies be conducted and used for EPA regulatory purposes only if: the study is "needed and scientifically appropriate," as further defined in the Report (Recommendation 3-1); for a study designed to relax public health protections by reducing the interspecies uncertainty factor, the experiment presents "a reasonable certainty of no harm to study participants" (Recommendation 4-1); and the study

satisfies the highest ethical standards by, among other things, ensuring "free and informed consent of participants" (Recommendation 5-1). A129-43.

Not long after the National Academy completed its investigation, EPA announced that it would "generally accept" third-party human studies that the Agency deemed scientifically valid "unless there is clear evidence that the conduct of these studies was fundamentally unethical . . . or was significantly deficient relative to the ethical standards prevailing at the time the study was conducted." A337. EPA also announced that it planned "to publish a proposed rule to make the provisions of the Common Rule applicable to certain newly conducted third-party human studies." *Id.* EPA stated it would "consider" the Academy's Report, but made no commitment to follow the Report's seventeen Recommendations. *Id.*

Several months later, the House of Representatives took up EPA's fiscal year appropriation bill. During the floor debates, Representatives Solis and Bishop introduced an amendment designed to bar EPA from using appropriated funds to rely on "third party intentional dosing human studies for pesticides." 151 Cong. Rec. H3670-H3671 (May 19, 2005). Rep. Solis explained that, although EPA's own Administrator had testified that EPA had "more than sufficient" data "to protect the health of the public, without human studies," EPA had nevertheless "chosen to go against the recommendations of the National Academy of Sciences" and to accept many "outside studies which . . . fail to meet minimum international

standards established in the Nuremberg Code and in the Helsinki Declaration of the World Medical Association." 151 Cong. Rec. H3671. The Bishop-Solis amendment passed the House of Representatives on a voice vote without opposition. *Id.* The following month, before this legislation reached the Senate, staff to Senator Boxer and Representative Waxman issued a detailed report on *Human Pesticide Experiments* that criticized EPA for "not follow[ing] the recommendations put forward by the National Academy of Sciences." A674.

Despite these indicia of congressional concern, EPA continued work on its own human testing proposal. In June 2005, a "Final Agency Review Draft" of an EPA human testing rule was made available to Members of Congress. A576. The draft rule would have extended the provisions of Common Rule Subpart A, already applicable to EPA's own research, to certain third-party research. A588, 590. The draft rule would not, however, have adopted many of the Recommendations of the National Academy of Sciences' 2004 Report. *Compare* A622-35 (draft rule) *with* A129-43 (NAS Recommendations). For example, the draft rule would not have provided criteria or guidelines for determining whether an experiment included "representative study populations" or had "adequate statistical power." A204 (NAS Recommendation 3-1). The draft rule also would not have prohibited all third-party intentional dosing toxicity studies for pesticides on pregnant women and children, but would instead have restricted such experiments only if the

research had been conducted with an intention to submit the results to EPA under FIFRA or FFDCA § 408. A588, 599-600, 603-05, 622, 625-28, 628-629.

Later that month, the Senate began debate on EPA's fiscal year 2006 appropriations bill. Both Senator Boxer and Senator Burns proposed amendments related to human testing. Senator Boxer's amendment, like that passed by the House, would have restricted all "third-party intentional-dosing human studies for pesticides." 151 Cong. Rec. S7553 (June 29, 2005). Senator Burns' amendment, presented as an alternative to Senator Boxer's, 151 Cong. Rec. S5556-57 (June 29, 2005), would more narrowly have applied only to "third-party intentional human dosing studies . . . currently *submitted to the Agency under FIFRA*." 151 Cong. Rec. S7552 (June 29, 2005) (emphasis added). Both amendments passed, although Senator Boxer's amendment commanded a wider margin. 151 Cong. Rec. S7560-61 (June 29, 2005).

The EPA appropriations bill then went to a House-Senate Conference. The Conference Report rejected the narrower scope of Senator Burns' amendment and instead imposed a funding moratorium on EPA's use of any "third-party intentional dosing human toxicity studies for pesticides." A638. The Conference Report also required EPA to issue a rule to regulate both researchers' conduct and EPA's use of such studies. As finally enacted, the statute states, in full:

> Sec. 201. None of the funds made available by this Act may be used by the Administrator of the Environmental Protection Agency to accept,

> consider, or rely on third-party intentional dosing human toxicity studies for pesticides, or to conduct intentional dosing human toxicity studies for pesticides until the Administrator issues a final rulemaking on this subject. The Administrator shall allow for a period of not less than 90 days for public comment on the Agency's proposed rule before issuing a final rule. Such rule shall not permit the use of pregnant women, infants or children as subjects; shall be consistent with the principles proposed in the 2004 report of the National Academy of Sciences on intentional human dosing and the principles of the Nuremberg Code with respect to human experimentation; and shall establish an independent Human Subjects Review Board. The final rule shall be issued no later than 180-days after enactment of this Act.

SPA1. On August 2, 2005, President Bush signed Section 201 into law. A492.

D. EPA's Human Testing Rule

EPA published its final Human Testing Rule on February 6, 2006. SPA3, 7; A104, 335, 571, 722. The rule adopts most of the general concepts of the final agency review draft that had preceded enactment of Section 201. SPA8-10. Thus, the final Rule restricts third-party pesticide toxicity experimentation on pregnant women and children only if the researcher or study sponsor "intends" to submit the results to EPA for consideration under FIFRA or FFDCA § 408.[6] SPA16, 40. The final Rule also extends Common Rule Subpart A protections to pesticide-industry toxicity studies on people, SPA12-13, 36-40, and provides for prior review of study protocols by a Human Studies Review Board, SPA 24, 42. The final Rule

---

[6] Subparts K and L of the Rule apply when the researcher "intended" either to "submit" the results to EPA for consideration under FIFRA or FFDCA § 408, or to "hold" the results for EPA's "later inspection" under these statutes. SPA36 (§ 26.1201), 40 (§ 26.1201). For brevity, we describe these parts as applying to research intended to be "submitted" to EPA for consideration under FIFRA and FFDCA § 408.

does not, however, ban all intentional human dosing toxicity studies for pesticides on pregnant women and children; does not adopt many of the National Academy's Recommendations, and does not incorporate or follow the standards of the Nuremberg Code. In short, EPA unlawfully ignored Section 201's commands.

SUMMARY OF ARGUMENT

In August 2005, after a draft of EPA's human testing rule became public, Congress imposed a funding moratorium on EPA's use or consideration of human toxicity tests for pesticides until EPA promulgated a rule that: (1) "shall not permit the use of pregnant women, infants and children as subjects" in intentional dosing human toxicity studies for pesticides; (2) "shall be consistent with the principles proposed in the 2004 report of the National Academy of Sciences on intentional human dosing"; and (3) "shall be consistent with . . . the principles of the Nuremberg Code with respect to human experimentation." SPA1. The Human Testing Rule violates each of these requirements.

First, the Human Testing Rule does not bar "use of pregnant women, infants, and children as subjects" in all intentional human dosing pesticide toxicity experiments, as required by Section 201. Instead, the Rule bars only those studies that a third-party researcher or study sponsor intends to submit to EPA for use under either of two statutes, FIFRA or FFDCA § 408. SPA 40 (40 C.F.R. § 26.1201). The Rule thus does not restrict pesticide toxicity experimentation on

pregnant women and children if the researcher intends to publish the results in a journal, intends to submit the results to a state regulatory agency or foreign authority, or even intends to submit the results to EPA for use under some statute other than FIFRA and FFDCA § 408. The Human Testing Rule also allows EPA to rely on such an experiment for any purpose other than in an action under FIFRA or FFDCA § 408. SPA42 (40 C.F.R. §§ 26.1701, 26.1703). Section 201 does not countenance such exceptions.

Second, the Human Testing Rule contravenes Section 201's requirement of consistency with the principles proposed by the National Academy's 2004 Report. SPA1. The Academy's proposals are clearly set forth in seventeen, enumerated Recommendations. These Recommendations propose, for example, that EPA promulgate criteria to determine the scientific validity of human dosing research; that EPA bar experiments conducted for the purpose of justifying relaxed regulatory protections if those experiments place human subjects at risk; and that EPA not use previously conducted pesticide studies if those studies violated the ethical norms that prevailed when the studies were conducted. EPA's Rule either entirely ignores or expressly departs from each of these principles.

Third, the Human Testing Rule violates Section 201's requirement of consistency with the Nuremberg Code. The Code's first and most fundamental principle is that no experiment may be conducted on a human being unless that

human being has the "legal capacity to give consent" and has given that consent "without the intervention of any element of force . . . or other ulterior form of constraint or coercion." A529. This Nuremberg Code requirement is echoed in FIFRA § 12(a)(2)(P), 7 U.S.C. § 136j(a)(2)(P), which also requires the consent of "such human being" on whom the experimentation occurs. EPA's Rule violates these statutory requirements by adopting the far more lenient, pre-existing Common Rule consent standard. A1277. The Human Testing Rule also violates other aspects of the Nuremberg Code, as well as parallel principles of the National Academy's Report, including the principles that human experiments should not be conducted unless necessary and based on prior research.

STANDARD OF REVIEW

Judicial review of EPA's final human testing rule is governed by the standards articulated in section 10 of the Administrative Procedure Act ("APA"), 5 U.S.C. § 706(2)(A), which provides that a reviewing court "shall hold unlawful and set aside" agency action that is "arbitrary, capricious, . . . or otherwise not in accordance with law." *See New York Pub. Interest Research Group v. Johnson*, 427 F.3d 172, 179 (2d Cir. 2005) (holding that, where the underlying statute provides no standard of review, agency action is reviewed under APA standards). The present case turns largely on the latter part of this standard – whether EPA's rule is "not in accordance with law," 5 U.S.C. § 706(2) – and in particular, on the

meaning of Section 201 of EPA's fiscal year 2006 appropriations act, SPA1, and section 12(a)(2)(P) of FIFRA, 7 U.S.C. § 136j(a)(2)(P). EPA's construction of these statutes is reviewed under the familiar framework of *Chevron U.S.A., Inc. v. Natural Resources Defense Council*, 467 U.S. 837 (1984), and progeny.

Under *Chevron*, "[t]he judiciary is the final authority on issues of statutory construction." 467 U.S. at 843 n.9; *see also* 5 U.S.C. § 706 ("[T]he reviewing court [that] shall decide all relevant questions of law...."). Thus, under *Chevron*'s "step one," this Court should first "employ[] traditional tools of statutory construction" and "reject administrative constructions which are contrary to clear congressional intent." *Chevron*, 467 U.S. at 843 n.9. If Congress has "explicitly left a gap for the [implementing] agency to fill," then under *Chevron's* "step two," an agency's reasonable construction of the statute through formal rulemaking may be "given controlling weight unless arbitrary, capricious, or manifestly contrary to the statute." *Id.* at 843-44. However, deference to an agency construction "is called for only when the devices of judicial construction have been tried and found to yield no clear sense of congressional intent." *General Dynamics Land Sys., Inc. v. Cline*, 540 U.S. 581, 600 (2004); *accord Protection & Advocacy for Persons*

With Disabilities v. Mental Health & Addiction Servs., 448 F.3d 119, 128 (2nd Cir. 2006).[7]

ARGUMENT

I. The Rule Unlawfully Allows Intentional Pesticide Toxicity Experiments on Pregnant Women, Infants, and Children, in Violation of Section 201

History teaches that toxicity experiments on pregnant women, infants, and children often raise serious ethical concerns. In one study, sixteen families in Tucson, Arizona, were exposed in their home to the pesticide dichlorovos (DDVP) over a six month period; among those exposed were 35 children, some as young as 2 years old. A693. In another study, pregnant women and infants in a maternity ward, as well as sick children and men with liver disease, were exposed, reportedly without their knowledge, to the same pesticide; many exhibited adverse symptoms. A429. Of course, children, infants, and the unborn cannot consent to such experimentation, and may be at higher risk during their development. A154.

Through Section 201, Congress sought to end such studies. Congress directed EPA to "not permit the use of pregnant women, infants, or children as

---

[7] The APA's "arbitrary and capricious" standard applies to issues other than statutory interpretation. *See Forest Watch v. United States Forest Serv.*, 410 F.3d 115, 118-19 (2d Cir. 2005). Under this standard, a court must ensure that the agency "examine[d] the relevant data and articulate[d] a satisfactory explanation for its action," including "a rational connection between the facts found and the choice made." *Motor Vehicle Mfrs. Ass'n v. State Farm Mutual Auto. Ins. Co.*, 463 U.S. 29, 43 (1983) (internal quotation marks and citation omitted). The issues in this case are principally matters of statutory construction to which this "arbitrary and capricious" standard is inapposite.

subjects" in "intentional dosing human toxicity studies for pesticides." SPA1. This categorical requirement includes no exceptions.

EPA, however, chose to restrict chemical industry toxicity experiments on pregnant women and children only where the researcher "intended" to submit the research to EPA, and then only if submitted under one of two statutes, FIFRA or FFDCA § 408. SPA40. Research not covered by this intent requirement is not barred. Thus, the Human Testing Rule permits experiments on pregnant women, infants, or children to continue if the researcher intends to publish the research,[8] to submit the research to a state agency or other authority,[9] or to submit the experiment to EPA for the Agency's consideration under some law other than FIFRA or FFDCA § 408, such as the Safe Drinking Water Act, the Clean Water Act, or the hazardous waste laws. *See supra*, at 9-10; SPA12-13, 16, 36-40. The

---

[8] Petitioners have moved to complete the administrative record with notes of an EPA meeting on the Human Testing Rule that appear to show that EPA was aware that a pesticide company may have "laundered" human experiments through a foreign university. *See* Wall Decl. (Sept. 28, 2006), Ex. D at 4 ("intent-Monsanto launders study thru Univ Bangalore"). This document, which is properly part of the administrative record because it reflects evidence before the Agency during the rulemaking, suggests that EPA was aware that the Human Testing Rule's "intent" requirement could create a loophole to Section 201's ban on toxicity testing on pregnant women, infants, or children.

[9] State regulatory agencies conduct separate risk assessments of pesticides. *See, e.g.*, AR EPA-HQ-2003-0132-0163 (California Department of Pesticide Regulation risk characterization document for azinphos-methyl) (available at www.regulations.gov); *see generally* 7 U.S.C. § 136v (preserving certain state authority over pesticide regulation).

Rule also allows EPA to rely on toxicity experiments on pregnant women, infants, or children for any action not taken under FIFRA or FFDCA § 408.[10] SPA42.

These limitations cannot be reconciled with Section 201. Congress directed that EPA "shall not permit" the "use of pregnant women, infants and children as subjects" in "intentional dosing human toxicity studies for pesticides" – at all. SPA1. Section 201's language is neither qualified nor precatory. It does not distinguish experiments conducted under FIFRA from those conducted under the Safe Drinking Water Act, or studies conducted for EPA as opposed to studies conducted for publication.

In August 2005, EPA quietly met in the President's Office of Management and Budget with representatives of the pesticide industry to discuss the human testing rulemaking. According to handwritten notes of the meeting, an official from the pesticide trade association told EPA "*never say never*" to testing on "kids." A402 (emphasis in original). EPA seems to have followed the pesticide industry's advice. That advise was, however, contrary to Section 201.

EPA's present explanation for why it did not impose such a ban rests on a perplexing theory that the statutory phrase "studies for pesticides" really means

---

[10] EPA's rule not only fails to prohibit intentional dosing of pregnant women and children with pesticides in non-"covered" toxicity studies, the rule fails even to apply to third-party research the special protections for pregnant women, infants, and children that HHS adopted in Subparts B and D of the Common Rule, *see* 45 C.F.R. §§ 46.201-.207, 46.401-.409.

"studies that are intended for consideration by EPA under [FIFRA and FFDCA § 408]." SPA29-30. "Studies for pesticides" has no such meaning. In ordinary usage, *see Engine Mfrs. Ass'n v. South Coast Air Quality Management Dist.*, 541 U.S. 246, 252 (2004), "studies for pesticides" means "studies with regard or respect to pesticides." *See Random House Unabridged Dictionary* 747 (2d ed. 1993) (defining "for"). When the Conferees rejected Senator Burns' amendment, they consciously decided not to limit Section 201 to studies submitted under FIFRA. *See supra*, at 21.[11]

In short, EPA's construction ignores Justice Frankfurter's three principles of statutory interpretation: "'(1) Read the statute; (2) read the statute; (3) read the statute.'" *See Wickwire Gavin v. United States Postal Service*, 356 F.3d 588, 594 (4th Cir. 2004) (citation omitted). Because the Human Testing Rule violates Congress' clear command, it should now be set aside. *See United States v. Ron*

[11] The Senate debates suggest that a principal goal of Senator Boxer's amendment (which, similarly to Section 201, covered all "third-party intentional human dosing studies for pesticides") was to prevent EPA from finalizing the narrower approach of its draft rule that allowed some continued experimentation on pregnant women and children. *See, e.g.*, 151 Cong. Rec. S7559 (June 29, 2005) (Sen. Boxer statement criticizing Burns' amendment for "support[ing] an EPA regulation that says there will be a limited number of scientific studies involving pregnant women, fetuses, newborn babies of uncertain viability or nonviable newborns"); *id* at S7560 (similar); *id* at S7556 (Sen. Clinton statement that "EPA should not be using these flawed studies *in any way*") (emphasis added).

Pair Enters., Inc., 489 U.S. 235, 241 (1989); *United States v. Rutherford*, 442 U.S. 544, 555 (1979); *Linea Area Nacional de Chile*, 65 F.3d at 1040.[12]

II. The Rule Unlawfully Departs from the National Academy's Proposed Scientific and Ethical Principles, in Violation of Section 201

A. The Rule Is Inconsistent with the National Academy's Proposed Principles

After carefully reviewing the history of human testing and EPA's existing regulatory framework, the National Academy of Sciences' 2004 Report made seventeen Recommendations. These Recommendations do not preclude all human toxicity experimentation, but set forth proposed principles, A130-143, to ensure that such experiments proceed only with "utmost caution and care," A146. To ensure "scientific validity," for example, Recommendation 3-1 proposed that EPA issue guidelines "for determining whether intentional human dosing studies . . . include representative study populations for the endpoint in question, and . . . meet requirements for adequate statistical power." A203-04. Recommendation 4-1 proposed that a study "intended to reduce the interspecies uncertainty factor . . . could be justified ethically only if the participants' exposure to the pesticide could

[12] Petitioners have moved to complete the administrative record with an EPA guidance memorandum on implementation of Section 201 that shows EPA did not always hold its present, implausible interpretation of the phrase "studies for pesticides." The guidance reveals that, soon after Section 201's enactment, EPA concluded that a study *of* a pesticide was a study "for pesticides" – even if not "submitted or otherwise available for consideration under [FIFRA or FFDCA § 408]." *See* Wall Decl. (Sept. 28, 2006), Ex. A-1 at 14-15.

reliably be anticipated to pose no identifiable risk or present a reasonable certainty of no harm to study participants." A227-28. Recommendation 5-7 proposed that EPA reject previously conducted studies if there was "clear and convincing evidence that the conduct of those studies . . . was deficient relative to then-prevailing ethical standards." A252.

In Section 201, Congress directed EPA to promulgate a rule that "shall be consistent with the principles proposed in the 2004 report of the National Academy of Sciences on intentional human dosing."[13] SPA1. The Human Testing Rule violates this requirement by ignoring or departing from many of the Academy's proposals. Because of its limited scope, the Rule provides no safeguards at all – let alone those proposed by the National Academy – as to third-party intentional dosing pesticide toxicity research that is not intended to be submitted to EPA for consideration under FIFRA or FFDCA § 408. *See* SPA36, 40. In this respect, the Rule violates Section 201's requirement of consistency with the National Academy's proposed principles for the same reasons discussed, *supra*, at 29-30: Section 201 applies to *all* "intentional human dosing toxicity studies for pesticides," not only those submitted under FIFRA or FFDCA § 408.

The Human Testing Rule fails to ensure consistency with the National Academy's proposed principles, however, even as to those experiments it does

[13] "Consistent" means "agreeing or accordant." *See Random House Unabridged Dictionary* 434 (2d ed. 1993).

cover. EPA concedes that it has not tried to implement those Recommendations, choosing instead to re-interpret Congress' command of "consisten[cy] with the principles proposed in the 2004 report of the National Academy of Sciences" as requiring something entirely different. Because the Human Testing Rule is inconsistent with the Academy's proposals, the Rule violates Section 201.[14]

1. The Rule Unlawfully Ignores the National Academy's Call for Rigorous Scientific Criteria to Justify Human Dosing Studies (Recommendations 3-1 and 5-1)

If a human experiment "cannot make a scientifically sound contribution to regulatory decision making," then it cannot justify subjecting human beings to any level of risk. *See* A189, A233 & n.1. To address this issue, the National Academy's Recommendation 3-1, entitled "Scientific Validity of Intentional Human Dosing Studies," proposed that EPA issue guidelines "for determining whether intentional human dosing studies have been . . . designed . . . to . . . include representative study populations for the endpoint in question, and . . . meet requirements for adequate statistical power." A203-04. Recommendation 5-1 establishes that "[n]ecessary conditions for scientifically and ethically acceptable intentional human dosing studies include . . . a research design and statistical

[14] EPA's Rule also violates the APA requirement that an agency "consider the relevant factors" and draw "a rational connection between the facts found and the choice made." *Motor Vehicle Mfrs. Ass'n*, 463 U.S. at 43. The "relevant factors" here included the 17 specific NAS Recommendations with which Section 201 required the rule to be consistent. EPA never attempted to explain how its Rule might be consistent with each of those Recommendations. A1281-82.

analysis that are adequate to address an important scientific or policy question, including adequate power to detect appropriate effects" – and studies that do not meet these standards "should not be carried out or accepted by EPA as input to the regulatory decision-making process." A235-26. The Human Testing Rule is inconsistent with the Academy's proposed principles.

The history of human experimentation is not one of notable scientific rigor. Human testing researchers have often, and inexplicably, discounted widespread adverse health effects among the human subjects, A668, 690-92; conducted studies on human subjects who were not representative of the populations at risk, A30, 31-32, 422, 426; and recruited so few subjects that the study lacked the statistical muscle needed to determine toxic effects that could be found across a broader population, A60-62. Examining EPA's own practice with respect to human research, the National Academy stated that "EPA should introduce much greater scientific care and rigor into its process for considering and relying on intentional human dosing studies by establishing criteria and procedures for deciding when and how they are to be conducted and their results used." A189; *see also* A233 at n.1 ("'[R]esearch protocols . . . with sample sizes inadequate to support reasonable inferences about the matter in question, are unjustifiable.'") (citation omitted); A60-61 (EPA science advisory panel report), A691 (Boxer-Waxman Report).

Recommendation 3-1 and 5-1 address these concerns. Recommendation 3-1(b), for example, provides for EPA to issue standards to determine whether studies meet criteria of "adequate statistical power" and "representative study populations for the endpoint in question." A203-04. Similarly, Recommendation 5-1 proposes that studies be required to include "statistical analysis that are adequate to address an important scientific or policy question, including adequate power to detect appropriate effects." A236. The Report makes other scientific Recommendations as well. *See, e.g.*, A273, 278.[15]

The Human Testing Rule neither adopts such criteria for assessing scientific validity nor provides guidelines to ensure that studies are conducted and considered in a manner consistent with the Academy's proposals. SPA26. It does not specify that studies must have "adequate statistical power" or "adequate power to detect appropriate effects," for example. Indeed, the Rule does not address the issues of statistical power, representative study populations, or other scientific

---

[15] For example, Recommendation 3-1, proposed that EPA issue "guidelines for determining whether intentional human dosing studies have been . . . justified, in advance of being conducted, as *needed* and scientifically appropriate, in that they could contribute to addressing an important scientific or policy question that *cannot be resolved on the basis of animal data or human observational data*." A203-04 (emphasis added). Recommendation 5-1 establishes that "[n]ecessary condition[s]" for intentional human dosing studies include: "*prior animal studies*," a *demonstrated need* for the knowledge to be obtained," and "*free and informed consent of participants*." A236 (emphasis added). The Human Testing Rule's failure to implement these principles is discussed, *infra*, at 52, 55-58, in tandem with parallel principles of the Nuremberg Code.

criteria at all. The Human Testing Rule instead adopts the Common Rule's pre-existing procedural requirement that IRBs review studies for "sound research design," without defining that term. SPA 38. This is the same standard that EPA had long applied to its own research, 40 C.F.R. § 26.111(a)(1)(i), and which the National Academy necessarily found inadequate when it recommended that EPA issue guidelines for determining whether a study had adequate statistical power, A203-04; *see also* A189 (suggesting that EPA "introduce much greater scientific care and rigor into [EPA's] process of considering and relying on intentional human dosing studies").

Section 201 requires that the Human Testing Rule "shall be consistent" with the NAS Report's Recommendations. Recommendations 3-1 and 5-1 required the Agency to establish and implement criteria for scientific validity. EPA rejected that proposal, claiming that scientific validity is "necessarily a case-by-case judgment" that could not be assessed through issuance of guidelines as the National Academy had proposed. SPA26. Because the Rule is inconsistent with NAS Recommendations 3-1 and 5-1, it violates Section 201 and should be set aside.

2. The Rule Unlawfully Authorizes Experiments that Place Human Beings at Risk Absent Overriding Health or Environmental Justification (Recommendations 4-1 & 4-2)

After carefully reviewing the history of human testing, the National Academy concluded in its Recommendation 4-1 that some chemical industry experiments – those that place human beings at potential risk solely in an effort to develop evidence to justify relaxed human health standards – are never ethical. A227-28. Such studies may improve the companies' sales, and sometimes may refine scientific knowledge, but these purposes, the Academy concluded, would not justify intentionally dosing a human being with potentially harmful toxins. A209. The Human Testing Rule is contrary to law because it is inconsistent with this principle.

The National Academy of Sciences distinguished among three different types of intentional human dosing studies, each of which poses a different level of risk. The most benign category of human studies (the "pharmokinetic" or "PK" study) involves doses of chemicals that are so minute that they are known, from extensive previous animal testing, to have no biological effect at all; these studies simply trace what happens to these chemicals after they enter the human body. A191. Because the quantities administered have no biological effect, they pose "no identifiable risk" to human subjects. A191, 225. A second type of dosing study (the low-dose "pharmacodynamic" "PD," or "toxicodynamic" study)

measures how pesticides affect the human body, A192, but involves such small doses that, based on extensive prior animal research and human observational studies, scientists can reasonably conclude the exposure presents a "reasonable certainty of no harm to study participants." A225, 192.

A third group of studies, however, involves dosing humans with pesticides in concentrations that are specifically intended to measure "a clinically detectable, adverse effect." A193. For example, in one such study, investigators administered the pesticide carbofuran to nine human beings for the express purpose of determining "the minimum dose necessary to induce toxic effects (e.g., headaches, nausea, and vomiting)" in healthy male subjects. Such effects apparently occurred, as three of the nine human subjects experienced heart arrhythmias. A691-93. In another intentional toxicity study, the fumigant chloropicrin – used as a chemical warfare agent during World War I – was administered to 127 young adults, some of whom were placed in a vapor "chamber" for hour-long periods on consecutive days, where they were exposed to chloropicrin concentrations half again as high as the highest average dose allowed by the Occupational Health and Safety Administration over an eight-hour day. A683-84. About ten percent of these "chamber" subjects reported effects that the study classified as "severe." *Id.*

Studies in this third group are *intended* to induce and evaluate toxic effects in humans and thus, by design, pose "an identifiable risk to study participants."

A225, 193. Where such pesticide experiments are conducted for the purpose of justifying reduced human health protections by reducing the interspecies uncertainty factor, the risk to human subjects is not counterbalanced by any potential medical benefit to the subject. Rather, "the interest of the study sponsor is to increase the RfD [*i.e.*, the level deemed 'safe'] and thus allow for greater use of the pesticide."[16] A227.

With respect to this last category of human dosing studies, the Academy's Recommendation 4-1 articulated a bright line: "a human dosing study intended to reduce the interspecies uncertainty factor . . . could be justified ethically only if the participants' exposure to the pesticide could reliably be anticipated to pose no identifiable risk or present a reasonable certainty of no harm to study participants." A227-28. Similarly, Recommendation 4-2 provides that "[n]o study is ethically justifiable if it is expected to cause lasting harm to study participants." A228.

EPA's Human Testing Rule is inconsistent with these principles. Instead of adopting the bright lines set forth in Recommendations 4-1 and 4-2, the Human Testing Rule adopts a provision from the earlier Common Rule under which a panel reviews each study to determine whether "[r]isks to subjects are reasonable

---

[16] *Cf.* A412 (interagency comments of National Institutes of Health) ("[A] human toxicity study conducted by a pesticide company which is designed to measure effects of pesticide exposure in order to obtain EPA approval for marketing of that pesticide has a purpose that is fundamentally not related to the improvement of public health.").

in relation to anticipated benefits, if any, to subjects, and the importance of the knowledge that may reasonably be expected to result." SPA38. This standard directs a review panel to balance risks to the human subject against "the importance of the knowledge" an experiment might provide. SPA38. Such a balancing approach cannot be reconciled with Recommendations 4-1 and 4-2, under which "importance of knowledge" is not a relevant factor and certainly not a factor that could justify subjecting human beings to risk of harm.[17] The Rule's inconsistency with Recommendations 4-1 and 4-2 is contrary to law.

3. The Rule Unlawfully Allows EPA to Rely on Human Tests that Violate Applicable Ethical Standards (Recommendation 5-7)

While most of the National Academy's Recommendations apply only prospectively, to future research, the Academy also addressed the "particularly vexing" question of how and whether EPA should rely on several dozen previously conducted pesticide studies that do not meet present ethical norms.[18] A251-52. The Academy's conclusion, set forth in Recommendation 5-7, was that while EPA should not entirely reject such older studies, EPA should not rely on a study if

---

[17] EPA's rule provides for IRB review to ensure that"[r]isks to subjects are minimized." SPA38. Risks may be "minimized," however, without ensuring that the study presents a "reasonable certainty of no harm." A228. The very *purpose* of the toxicity studies at which the NAS Report is directed is to induce and measure potentially harmful effects. A193, 201.

[18] EPA's rule preamble indicates that EPA received 33 intentional dosing studies over the period 1996 to 2001. SPA7.

clear and convincing evidence showed that it was either "fundamentally unethical" or "deficient relative to then-prevailing ethical standards." A252.

EPA chose not to adopt the Academy's proposed principle. Instead, EPA's Rule adds a critical word to the second, "deficiency" prong of the Academy's test to allow EPA to consider a study that *was* ethically deficient when conducted, so long as the study was not "*significantly* deficient" under then-prevailing standards. SPA42 (emphasis added). EPA's insertion of the word "significantly" into the Academy's proposed principle materially changes its meaning. Although EPA has declined to define the universe of ethical misconduct that is "deficient" but not "significantly deficient," EPA has stated that this modification reflects "EPA's view that refusing to rely on data is a drastic action – one that should be reserved for the *most egregious* of conduct."[19] A613 (emphasis added).

Under this modified standard, the Human Testing Rule allows EPA to rely on existing human studies even where clear and convincing evidence demonstrates that these studies were "deficient" relative to then-prevailing ethical norms. Under the Academy's proposed principle, however, EPA could not use such studies. *Cf.* A660 (report of Sen. Boxer and Rep. Solis stating that EPA's proposed insertion of

[19] In responding to comments on a different aspect of this rulemaking, EPA made clear that a human experiment could be in "substantial compliance" with the rule's standards "even if there were deficiencies in informed consent." A1149. If informed consent deficiencies are not "substantial," in EPA's view, then they likely are not "significant," in EPA's view, either.

"significantly" into the standard for consideration of "old unethical experiments" would improperly modify the NAS's proposed standard). Because the Human Testing Rule allows EPA to consider research in a manner that is inconsistent with the Academy's proposal, it violates Section 201.

4. The Rule Unlawfully Fails to Ensure that Researchers Pay for Injured Subjects' Medical Care (Recommendation 5-5)

Recognizing the possibility that toxicity research on pesticides – some of which are little studied – could result in injury to human subjects, the National Academy proposed in Recommendation 5-5 that "sponsors of or institutions conducting intentional human dosing studies should ensure that participants receive needed medical care for injuries incurred in the study, without cost to the participants." A248. As the Academy explained, "the cost of research injuries should not be borne by the injured participants."[20] A247 (internal quote marks and citation omitted).

Contrary to the Academy's proposal, the Human Testing Rule makes no provision for medical care for human subjects injured in pesticide dosing experiments. Section 26.1111(a)(6) of the rule allows for "*monitoring* the data collected to ensure the safety of subjects." SPA38 (emphasis added). Monitoring, however, is not treatment; the Rule is silent as to who will pay for a trip to the

[20] The lack of alternative health care may be a particular concern among the persons most likely to submit to pesticide dosing experiments, in which payments sometimes may not exceed $15/hour. A683.

hospital. Because the Rule fails to ensure consistency with the Academy's Recommendation 5-5, it violates Section 201 and should be set aside.[21]

B. Section 201 Requires Consistency Between EPA's Rule and the National Academy's Recommendations

When Congress required EPA to promulgate a Rule that "shall be consistent with the principles proposed in the 2004 report of the National Academy of Sciences," there can be no serious doubt what Congress meant. Interpretation of this statutory phrase must begin, of course, with its ordinary meaning. *See Engine Mfrs. Ass'n*, 541 U.S. at 2522 (citation omitted); *accord S.D. Warren Co. v. Maine Bd. of Envtl. Prot.*, 126 S. Ct. 1843, 1847 (2006); *Raila v. United States*, 355 F.3d 118, 120 (2d Cir. 2004). The key words in this phrase are "principles," "proposed," and "National Academy of Sciences." In ordinary usage, "recommend" is a synonym of "propose," and "principle" means "something established as a standard or test, for measuring, regulating, or guiding conduct or practice." *Random House Unabridged Dictionary* 1539, 1551 (2d ed. 1993). Thus, the ordinary meaning of the phrase "principles proposed in the 2004 report of the National Academy of Sciences" would be "standards recommended in the 2004 report of the National Academy of Sciences." *See id.* at 1539, 1551. Those

---

[21] This aspect of the rule also is inconsistent with the Nuremberg Code's seventh principle, which requires that "[p]roper preparations should be made and adequate facilities provided to protect the experimental subject against even remote possibilities of injury, disability or death." A528.

"standards recommended" are plainly set forth in the Report's seventeen, enumerated Recommendations.

This interpretation of the phrase "principles proposed" is reinforced by the Academy's own use of the key words "recommendations," "proposals," and "principles." The Academy, for example, explicitly describes its seventeen Recommendations as "proposals." A129 ("[T]o be specific about the proposals being made, the recommendations follow."). The Report likewise uses the phrase "scientific and ethical *principles* described in earlier chapters" interchangeably with the phrase "substantive *recommendations* offered in earlier chapters." *Compare* A168 (emphasis added) *with* A265 (emphasis added). Thus, for the Academy like Congress, the Report's "recommendations" were its "proposals," and the Report's "scientific and ethical principles" were its "recommendations."[22]

The available legislative history further corroborates this interpretation. When the House debated the Conference Report into which Section 201 had been inserted, Representative Dicks (the ranking member of the House appropriations subcommittee for EPA and a manager of the House-Senate Conference) explained:

> [T]he conference report reflects the will of both the House and the Senate to stop such tests until the EPA develops regulations reflecting *the recommendations of the National Academy of Science* and follows the

[22] This obvious interpretation also is supported by Congress' parallel use of the word "principles" in Section 201, to refer to the 10 "principles" of the Nuremberg Code. SPA1; A529. The Nuremberg Code's 10 "principles" are structurally similar to the Academy's 17 Recommendations.

> Nuremberg protocols. In addition, these regulations will prohibit such testing on pregnant women, infants, and children.

A646. Representative Solis (the principal House proponent of this legislation) described this in detail:

> EPA circulated internally a draft rule among the agency's various offices on June 20, 2005. EPA's draft rule, slated for proposal next month, would have allowed the systematic testing of pesticides on humans. The draft rule does not comply with the *recommendations of the NAS* and the Nuremberg Code, and it contains multiple loopholes that invite abuse. . . .
>
> . . . The amendment that I am supporting today will ensure that EPA may not consider or rely on any intentional human-dosing study that does not meet *the minimum ethical and scientific criteria recommended by the NAS* and expressed in the Nuremberg Code.

A647-48 (emphasis added); *see also* A674 (Boxer-Waxman report criticizing EPA for "not follow[ing] the *recommendations* put forward by the National Academy of Sciences") (emphasis added).

In short, the "traditional tools of statutory construction," *Chevron*, 467 U.S. at 843 n.9 – legislative language and history – provide a "clear sense," *General Dynamics Land Sys.*, 540 U.S. at 600, that when Congress invoked the "principles proposed in the 2004 report of the National Academy of Sciences," Congress was referring to the Academy's seventeen Recommendations. Under *Chevron*'s "step one," *Nutritional Health Alliance v. FDA*, 318 F.3d 92, 99 (2d Cir. 2003), Congress' clear purpose ends the inquiry. *See General Dynamics Land Sys.*, 540 U.S. at 600; *Protection & Advocacy for Persons with Disabilities*, 448 F.3d at 128.

C. EPA's Construction of Section 201 Is Not Permissible

Notwithstanding either the ordinary meaning of Section 201's language or its legislative history, EPA argues that when Congress required conformance to the "principles proposed in the 2004 report of the National Academy of Sciences," Congress *really* meant to require consistency with the principles of a 1979 document known as the Belmont Report. The manifest problem with EPA's theory is that Congress did not mention the Belmont Report. If Congress had intended to require consistency with the Belmont Report's principles, and only those principles, Congress surely could have found a more obvious way of saying so.

Ignoring this difficulty, EPA weaves together a patchwork of quotes from a half-dozen scattered pages of the Academy's Report to try to show that "the 'principles proposed in the 2004 report of the National Academy of Sciences on intentional human dosing' are, in fact, the three fundamental principles of respect for persons, beneficence, and justice articulated in the Belmont Report . . . ." SPA30. While a few of EPA's piecemeal quotes do discuss the Belmont principles, those quotes simply do not support the weight of EPA's theory. The Academy's Report canvassed a wide array of prior "authoritative statements of principle." A127. These included the Belmont Report, SPA30, but also included many other existing ethical codes that EPA entirely ignores, including the Nuremberg Code, the Declaration of Helsinki, the FDA's good clinical practices

guidelines, the National Bioethics Advisory Commission's report, and several reports by the Institute of Medicine. *See, e.g.*, A125, 163, 170, 186, 207, 234, 253. The Academy expressly drew on these "many different sources" – not just the Belmont Report – in conducting its ethical analysis. A234. However, the Academy did not "propose" any of these ethical standards as *its* own comprehensive principles, let alone propose the Belmont Report principles as the *sole* principles that should govern human testing for EPA regulatory purposes. Indeed, when the Report first directly identified existing "authoritative statements of principle," it did not mention the Belmont Report at all. A128-29, 163.

Ultimately, the Academy concluded that the sundry pre-existing statements of principle – including those of the Belmont Report – were too "general" and too "unclear, indeterminate, inconsistent, and even contradictory" to provide the specific guidance required for EPA's consideration of intentional human dosing toxicity studies. A235. The Academy therefore "formulate[d] standards of ethical acceptability" reflecting its "own judgments." A234, 235. Those judgments – the Academy's "principles proposed" – are set forth in the Report's seventeen Recommendations. EPA's attempt to substitute the "unclear [and] indeterminate" principles of the Belmont Report ("respect," "beneficence," and "justice") for the

Report's Recommendations would turn the Report's conclusion that the existing principles were too indeterminate on its head.[23]

Thus, even if the language and history of Section 201 were not clear on their face, EPA's construction of the phrase "principles proposed in the 2004 report of the National Academy of Sciences" cannot be reconciled with an examination of that Report or Section 201 itself. Under *Chevron*'s "step two," *Nutritional Health Alliance*, 318 F.3d at 101-02, EPA's interpretation is not "reasonable" and therefore should be rejected. *See Levine v. Apker*, 455 F.3d 71, 80 (2d Cir. 2006); *see also Woodford v. Community Action of Greene County, Inc.*, 268 F.3d 51, 55-56 (2d Cir. 2001) (declining to defer to unreasonable agency interpretation of a statute).

[23] EPA's statutory theory also fails to account for the Academy's proposal of scientific as well as ethical principles. A163-64 ("principles of both ethical and scientific validity"); *see also* A168 (similar), A265 (similar). The Belmont Report does not speak directly to science at all. A1286. Nor does the NAS Report's chapter on "[s]cientific justification for and conduct of intentional human dosing studies" mention the Belmont Report. A189-204.

III. The Rule Is Unlawfully Inconsistent with the Nuremberg Code and Related Requirements

A. The Rule Unlawfully Authorizes Pesticide Toxicity Experiments on Humans Who Have Not Given Their Own Free and Fully Informed Consent, Contrary to the Nuremberg Code and Related Provisions of FIFRA and the NAS Report

At least since the Nazi doctors' trial at Nuremberg, Germany, the fully informed and voluntary consent of each human subject has widely been viewed as a critical element of any ethically conducted experimentation on humans. A243, 529. Unfortunately, the annals of subsequent human research are peppered with experiments in which voluntary, fully informed consent – as defined by the Nuremberg Code's first principle – was not obtained. These include pesticide experiments in which risk disclosures forms were inadequate, misleading, or even false. A244-45. For example, in one organophosphate pesticide study, the risk disclosure form began with the statement that "Low doses of these agents have been shown to improve performance on numerous tests of mental function," even though this is not true of organophospates.[24] A83; AR EPA-HQ-2003-0132-0520 (Dr. Alan H. Lockwood, "Human Testing of Pesticides: Ethical and Scientific

[24] Indeed, organophospates have the opposite effect. *See e.g.,* Joan Rothlein, *et al.*, "Organophosphate Pesticide Exposure and Neurobehavioral Performance in Agricultural and Nonagricultural Hispanic Workers," 114 *Envtl. Health Perspectives* 691-696 (2006) (finding that farmworkers exposed to low levels of organophosphate insecticides scored more poorly on neurobehavioral tests – including tests of attention and concentration – than did a comparable control group which did not have any such pesticide exposures).

Considerations," at 1909). Disclosures in two studies conducted in the 1990s for the pesticide amitraz misleadingly referred to this pesticide as a "drug." A687. Similarly, a 2004 study of the insecticide dimethoate included a consent disclosure form that advised participants that "not a single health effect is expected" – and stated that the chemical is "used to protect or cure all kinds of plants, fruits and crops from disease" – even though EPA has identified dimethoate as a suspected carcinogen and a developmental and neurological toxin. A686.

The Nuremberg Code's first principle unequivocally precludes such research conduct. It states:

> The voluntary consent of the human subject is absolutely essential. This means that the person involved [1] should have legal capacity to give consent; [2] should be so situated as to be able to exercise free power of choice, without the intervention of any element of force, fraud, deceit, duress, over-reaching, or other ulterior form of constraint or coercion; and [3] should have sufficient knowledge and comprehension of the elements of the subject matter involved as to enable him to make an understanding and enlightened decision. . . .

A529. This principle is echoed in the NAS Recommendation 5-1(f), which requires that "such human being ... freely volunteer" before being the subject of a pesticide toxicity experiment. SPA2.

The Human Testing Rule is inconsistent with each of these "informed consent" standards. For example, while the Nuremberg Code requires "consent of the human subject" who "should have legal capacity to give consent," A529, the Rule allows "consent" to be given by any "legally authorized representative" of the

subject. SPA39 (40 C.F.R. §§ 26.1116, 26.1117(a), (b)(1) & (b)(2)). EPA's rule defines a "legally authorized representative" as an "individual or judicial or other body authorized under applicable law to consent on the behalf of a prospective subject to the subject's participation in the procedure(s) involved in the research." SPA36 (40 C.F.R. § 26.1102(c)). The "applicable law" that defined which persons or entities can provide surrogate consent presumably includes not only the law of the various states, but also the law of any foreign country in which an experiment is conducted – including the laws of foreign countries that may not accept American concepts of individual rights or the necessity of individual consent.

The notion that a "legally authorized representative" might provide consent originated in the Common Rule, which the Department of Health and Human Services originally developed to guide medical research. *See* 45 C.F.R. § 46.102 (HHS Common Rule definition of "legally authorized representative"); A411 (interagency comments of the National Institutes of Health). Clinical medical trials may provide direct health benefits to a human being who is unable, due to incapacity or minority, to consent in person. To allow such research, Congress has expressly authorized consent to be given by a "representative" in trials of medical drugs and devices. *See* 21 U.S.C. § 355(i)(4); 21 U.S.C. § 360j(g)(3)(d).

However, in the quite different context of pesticide toxicity experiments with humans, which provide no medical benefits to the subjects, Congress has

never authorized consent to be given by a representative. Indeed, in FIFRA § 12(a)(2)(P), 7 U.S.C. § 136j(a)(2)(P)), Congress expressly prohibited pesticide tests on a human being absent the consent of "such human being." SPA2. FIFRA provides no exception for consent by a "representative," as is provided in the medical research statutes.

Thus, when Section 201 commanded consistency with the Nuremberg Code – which requires "[t]he voluntary consent of *the human subject*,"[25] A529 (emphasis added) – there is nothing to suggest that Congress meant anything other than what it wrote. Congress also required consistency with the National Academy's Report, of which Recommendation 5-1(f) demands "consent of *participants*," A236 (emphasis added), and which explains:

> [I]t is not justifiable to enroll persons who lack the capacity to consent to their involvement, *even if surrogate decision makers grant permission*, when the research offers them no prospect of direct personal benefit and carries more than minimal risk or when the needed information could be obtained through studies with individuals who have the capacity to consent.

A238 (emphasis added). The Human Testing Rule violates Section 201, because it expressly allows "consent" to be given by a "representative" other than the human

[25] The Nuremberg Code also makes clear that consent may not be provided on behalf of one who lacks capacity, stating that "*the person involved* should have legal capacity to give consent." A529 (emphasis added). In one of the few judicial decisions involving this issue, an unreported Detroit Michigan case from 1973 found that the Nuremberg Code required the consent of the human subject, not his parents, and that a human subject confined in a prison could not provide uncoerced consent. A383-84.

subject, in contravention of both the Nuremberg Code and the Academy's Recommendation 5-1(f). In this respect, the Rule also does "not accord[]" with law, 5 U.S.C. § 706(2)(a), as set forth in section 12(a)(2)(P) of FIFRA.

Nor is the Human Testing Rule consistent with the Nuremberg Code's requirement that "the person involved . . . should have sufficient knowledge and *comprehension* of the elements of the subject matter involved as to enable him to make an understanding and enlightened decision." A529 (emphasis added). The Rule adopted Common Rule standards for disclosure. The National Academy of Sciences' Report explains at length that these Common Rule disclosure standards are so inadequate that they have often led to "incomplete understanding or misunderstanding" among the human research subjects and that "those who agreed to participate in research often do not comprehend its basic features."[26] A244. By adopting these Common Rule standards, EPA was thus adopting standards that EPA knew would, in practice, often fail to ensure the test subject's "comprehension," as the Nuremberg Code demands. A529.

The Human Testing Rule also fails to follow the Nuremberg Code's requirement that a human subject must be "so situated as to be able to exercise free power of choice, *without the intervention of any element* of force, fraud, deceit,

[26] The National Academy suggested that EPA promulgate a set of informed consent "best practices," A245, perhaps including "a short multiple-choice test, which could indicate how well the participants understand the disclosed information," A244. EPA did not do so.

duress, over-reaching, or other ulterior form of constraint or coercion." A529 (emphasis added). Instead of adopting this standard, the Rule only requires that researchers seek informed consent in circumstances that "minimize the possibility of coercion." SPA39. While that may be a step in the right direction, an "element of . . . constraint or coercion," A529, may exist even where coercion has been, to some extent, "minimized." Moreover, the Rule's coercion "minimization" clause does not protect at all from other intrusions into voluntary consent under the Nuremberg Code, such as fraud, deceit, over-reaching, and constraint.[27]

The possibility of "constraint" infecting consent becomes most acute in the context of experiments on prisoners, which of course provided the original impetus for the Nuremberg Code's adoption. As EPA's June 20, 2005 draft rule concedes, "[s]ome of these studies have been submitted to [EPA] over the years, or retrieved from published sources, and some have been and continue to be relied on in [EPA] decision-making." A606. The record contains uncontroverted evidence – including a finding by the National Academy of Sciences, A238, and an unreported Michigan court decision, A383-84 – that prisoners, by virtue of their confinement, are inherently subject to constraint and vulnerable to coercion. Recognizing this,

[27] While the Rule calls for research review panels to include undefined "additional safeguards" to protect "the rights and welfare" of subjects who "are likely to be vulnerable to coercion or undue influence," SPA38, the Rule does not define these rights. The concept of "rights," and the related "additional safeguards" developed to protect those rights, is left entirely to the discretion of individual future researchers and review boards.

the Department of Health and Human Services, which authored the Common Rule standards that EPA's Rule adopts, called on EPA to go beyond those standards and ban prisoner pesticide dosing experiments entirely. A407. EPA did not do so.

In short, the Human Testing Rule fails to ensure consistency with the Nuremberg Code's prohibition on experiments on people who face "any element" of constraint and coercion. Particularly with respect to prisoners, the record does not support EPA's summary conclusion that its Rule meets this standard. Indeed, EPA itself concedes that it has not yet "reached a final position on . . . the need . . . for any additional protections for prisoners." SPA19. Because the Rule fails to ensure that consent is both genuinely informed and truly voluntary, within the meaning of the Nuremberg Code, it violates Section 201.

B. The Rule Fails to Ensure that Human Experiments Are Consistent with the Nuremberg Code's Third Principle, Which Requires a Human Experiment to Account for Prior Animal Research, and Related Provisions of the Academy's Recommendation 5-1

The Nuremberg Code's third principle requires that experiments on humans be "designed and based on the results of animal experimentation" and other knowledge such that the expected results will justify the human test. A529. Complementing this principle, the National Academy's Recommendation 5-1 states that "prior animal studies" are a "[n]ecessary condition[s]" for intentional human dosing studies. A236. These principles ensure that, before a human study

is conducted, a baseline of probable risks has been established through animal research so that humans are not subject to overly uncertain dangers.

The Human Testing Rule contains no precondition regarding prior animal research, or any other prior research. Indeed, EPA candidly concedes that the Rule's requirements "do not address [Nuremberg Code] principle 3 directly" at all. A1278. Although EPA suggests that those reviewing a human experiment protocol might be *able* to apply the Nuremberg Code principle, *id.*, the Rule does not require application of this principle and protocol review boards would be able to ignore it. Because the Rule does not ensure that human research will be based on the results of prior animal studies, it contravenes the Nuremberg Code's third principle and violates Section 201.

C. The Rule Fails to Ensure that Human Experiments Are Consistent with the Nuremberg Code's Second Principle and Related National Academy Recommendations that Bar Unnecessary Research on Human Subjects

The Nuremberg Code's second principle requires that human experimentation "should be such as to yield fruitful results . . . unprocurable by other methods or means of study, and not random and unnecessary in nature."[28] A529. This principle is complemented and reinforced by NAS Recommendation 3-1, which proposes criteria for determining whether intentional human dosing

[28] Similarly, the fourth Nuremberg principle states that "the experiment should be so conducted as to avoid all *unnecessary* physical and mental suffering and injury." *Id.* (emphasis added).

studies address "an important scientific or policy question that cannot be resolved on the basis of animal data or human observational data," and Recommendation 5-1, which identifies as a "necessary condition" for human experiments that there be "a demonstrated need for the knowledge to be obtained from intentional human dosing studies." A130, 133. The obvious purpose of these principles is to avoid subjecting humans to risk of harm absent a showing that dosing human beings with a toxin is, in fact, necessary.

It may be questioned whether such research is ever needed. EPA's Administrator testified during his confirmation hearings that "we have a more than sufficient database, through use of animal studies, to make licensing decisions that meet the standard, to protect the health of the public, without using human studies." 151 Cong. Rec. H3671 (May 19, 2005). The Administrator's testimony is confirmed by EPA's longstanding position that human studies are not needed to protect public health. A650.

Even if there are circumstances in which human toxicity research is "necessary," however, EPA's Rule fails to limit such experiments to those circumstances. Indeed, the Rule is entirely silent on the question of necessity. It requires no showing, nor indeed any inquiry, regarding the sufficiency of epidemiological or animal research. The Rule instead leaves the question whether an experiment is needed to the unfettered discretion of the pesticide manufacturers

who fund such studies. The Rule's failure to ensure consistency with the Nuremberg Code's necessity principle, as well as the National Academy's parallel Recommendations 3-1 and 5-1, violates Section 201.

CONCLUSION

For these reasons, this Court should set aside the Human Testing Rule and direct EPA to issue a new rule in accordance with law.

October 4, 2006 Respectfully Submitted,

By: 

Michael E. Wall
Aaron Colangelo
NATURAL RESOURCES DEFENSE COUNCIL
111 Sutter Street, 20th Floor
San Francisco, CA 94104
(415) 875-6100

Jan Hasselman
Patti Goldman
EARTHJUSTICE
705 Second Avenue, Suite 203
Seattle, WA 98104
(206) 343-7340

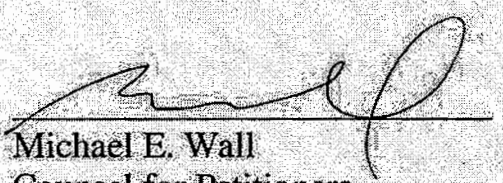
Shelley Davis
FARMWORKER JUSTICE FUND
1010 Vermont Ave., NW
Washington, DC 20005
(202) 783-2628

Counsel for Petitioners

Certificate of Compliance with Rule 32(a)

This brief complies with the type-volume limitation of Fed. R. App. P. 32(a)(7)(B) because it contains 13,394 words, excluding the parts of the brief exempted by Fed. R. App. P. 32(a)(7)(B)(iii). This brief complies with the typeface requirements of Fed. R. App. P. 32(a)(5) and the type style requirements of Fed. R. App. P. 32(a)(6) because it has been prepared in a proportionally spaced typeface using Microsoft Office Word 2003 in a 14 point, Times New Roman font.

October 4, 2006



Michael E. Wall
Counsel for Petitioners

CERTIFICATE OF SERVICE

The undersigned hereby certifies that she is an employee in the San Francisco Office of the Natural Resources Defense Council, 111 Sutter Street, 20th Floor, San Francisco, CA, 94104; is a person of such age and discretion to be competent to serve papers; and that on October 4, 2006 she served copies of the attached:

- Petitioners' Brief
- Appendix, Volume 1
- Appendix, Volume 2
- Special Appendix

by causing said copies to be placed in a prepaid or postpaid envelope addressed to the persons hereinafter named, at the places and addresses stated below, which are the last known addresses, and by either delivering said envelope to Federal Express for delivery or depositing said envelope and contents in the United States Mail at San Francisco, California, or by facsimile, e-mail, or hand delivery, as stated below:

Via Federal Express (and brief also via e-mail):

Alan D. Greenberg
U.S. Department of Justice
Environmental Defense Section
1961 Stout Street, 8th Floor
Denver, CO 80294
Alan.Greenberg@usdoj.gov

Patti Goldman & Jan Hasselman
Earthjustice
705 Second Avenue, Suite 203
Seattle, WA 98104
pgoldman@earthjustice.org & jhasselman@earthjustice.org

Shelley Davis
Farmworker Justice Fund
1010 Vermont Avenue, NW, Ste. 915
Washington, D.C. 20005
sdavis@nclr.org

Aaron Colangelo
NRDC
1200 New York Ave., NW. Ste 400
Washington, DC 20005
acolangelo@nrdc.org

I declare under penalty of perjury under the laws of the United States that the foregoing is true and correct.

Dated: October 4, 2006

Amy Macaux

UNITED STATES COURT OF APPEALS FOR THE SECOND CIRCUIT

Thurgood Marshall U.S. Courthouse at Foley Square 40 Centre Street, New York, NY 10007 Telephone: 212-857-8500

MOTION INFORMATION STATEMENT

Docket Number(s): 06-0820-ag (L), 06-1895-ag (CON), 06-2149-ag (CON), 06-2360-ag (CON)

Caption [use short title]

Natural Resources Defense Council

v.

United States Environmental Protection Agency

Motion for: Motion to Complete the Administrative Record

Set forth below precise, complete statement of relief sought:
An order directing completion of the administrative record with 5 documents attached as Exhibits A-1, A-2, B, C, and D to the Wall Declaration.

MOVING PARTY: Natural Resources Defense Council
- ☐ Plaintiff
- ☐ Defendant
- ☒ Appellant/Petitioner
- ☐ Appellee/Respondent

OPPOSING PARTY: U.S. Environmental Protection Agency

MOVING ATTORNEY: Michael Wall
[name of attorney, with firm, address, phone number and e-mail]
Michael Wall
Natural Resources Defense Council
111 Sutter Street, 20th Floor
San Francisco, CA 94104
(415) 876-6100 / mwall@nrdc.org

OPPOSING ATTORNEY [Name]: Alan D. Greenberg
[name of attorney, with firm, address, phone number and e-mail]
Alan D. Greenberg
United States Department of Justice
Environmental Defense Section
1961 Stout Street, 8th
Denver, CO 80294
(303) 844-1366 / alan.greenberg@usdoj.gov

Court-Judge/Agency appealed from: U.S. Environmental Protection Agency

Please check appropriate boxes:

Has consent of opposing counsel:
- A. been sought? ☒ Yes ☐ No
- B. been obtained? ☐ Yes ☒ No

Is oral argument requested? ☐ Yes ☒ No
(requests for oral argument will not necessarily be granted)

Has argument date of appeal been set? ☐ Yes ☒ No
If yes, enter date _____

FOR EMERGENCY MOTIONS, MOTIONS FOR STAYS AND INJUNCTIONS PENDING APPEAL:

Has request for relief been made below? ☐ Yes ☐ No

Has this relief been previously sought in this Court? ☐ Yes ☐ No

Requested return date and explanation of emergency:

Signature of Moving Attorney: _____ Date: 18 sept 2006

Has service been effected? ☒ Yes ☐ No
[Attach proof of service]

ORDER

IT IS HEREBY ORDERED THAT the motion is GRANTED DENIED.

FOR THE COURT:
ROSEANN B. MacKECHNIE, Clerk of Court

Date: _____

By: _____

Form T-1080 (Revised 10/31/02).

UNITED STATES COURT OF APPEALS
FOR THE SECOND CIRCUIT

NATURAL RESOURCES DEFENSE COUNCIL, INC.,	)	
Petitioner,	)	**No. 06-0820-ag (L)**
	)	No. 06-1895-ag (CON)
v.	)	No. 06-2149-ag (CON)
	)	No. 06-2360-ag (CON)
U.S. ENVIRONMENTAL PROTECTION AGENCY,	)	
Respondent.	)	

PETITIONERS' MOTION TO COMPLETE THE ADMINISTRATIVE RECORD

JAN HASSELMAN
PATTI GOLDMAN
Earthjustice
705 Second Avenue, Ste. 203
Seattle, WA 98104
Tel: (206) 343-7340

SHELLEY DAVIS
Farmworker Justice Fund
1010 Vermont Ave., NW, Ste. 915
Washington, DC 20005
Tel: (202) 783-2628

MICHAEL WALL
AARON COLANGELO
Natural Resources Defense Council
111 Sutter Street, 20th Floor
San Francisco, CA 94104
Tel: (415) 875-6100

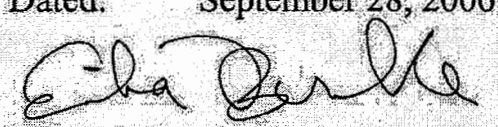
Counsel for Petitioners

Patti Goldman & Jan Hasselman
Earthjustice
705 Second Avenue, Suite 203
Seattle, WA 98104
pgoldman@earthjustice.org & jhasselman@earthjustice.org

Shelley Davis
Farmworker Justice Fund
1010 Vermont Avenue, NW, Ste. 915
Washington, D.C. 20005
sdavis@nclr.org

Aaron Colangelo
NRDC
1200 New York Ave., NW. Ste 400
Washington, DC 20005
acolangelo@nrdc.org

Dated: September 28, 2006



Erika Brekke

CERTIFICATE OF SERVICE

The undersigned hereby certifies that she is an employee in the San Francisco Office of the Natural Resources Defense Council, 111 Sutter Street, 20th Floor, San Francisco, CA, 94104; is a person of such age and discretion to be competent to serve papers; and that on September 28, 2006 she caused a true and correct copy of the foregoing:

- Petitioners' Motion to Complete the Administrative Record
- Declaration of Michael E. Wall in Support of Petitioners' Motion to Complete the Administrative Record (Attached to Motion)

to be placed in a prepaid or postpaid envelope addressed to the persons hereinafter named, at the places and addresses stated below, which are the last known addresses, and by either delivering said envelope to Federal Express for overnight delivery or depositing said envelope and contents in the United States Mail at San Francisco, California, or by facsimile, e-mail, or hand delivery, as stated below:

Via Federal Express and E-mail:

Alan D. Greenberg
U.S. Department of Justice
Environmental Defense Section
1961 Stout Street, 8th Floor
Denver, CO 80294
Alan.Greenberg@usdoj.gov

4. In July 2006, in the course of litigation over NRDC's Human Testing FOIA request, EPA released a privilege log describing a number of additional documents it intended to withhold or partially withhold from disclosure. The documents attached as Exhibit E to this Declaration are true and correct copies of excerpts from that privilege log.

5. In September 2006, NRDC received from EPA a supplemental response, dated August 30, 2006, to the Human Testing FOIA request. That response included documents referenced in EPA's July 2006 privilege log by document tracking numbers 119, 891, 1125, and 1308.

6. The documents attached as Exhibits A1, A2, B, and D to this Declaration are true and correct copies or excerpted copies of documents EPA provided to NRDC in its August 30, 2006 supplemental response to the Human Testing FOIA request as document numbers 119 (attached as Ex. A1), 891 (attached as Ex. A2), 1125 (excerpt attached as Ex. B), and 1308 (attached as Ex. D).

I declare under penalty of perjury that the foregoing is true and correct to the best of my knowledge, information, and belief.

Dated: San Francisco, California
September 28, 2006

Michael E. Wall

DECLARATION OF MICHAEL E. WALL IN SUPPORT OF PETITIONERS' MOTION TO COMPLETE THE ADMINISTRATIVE RECORD

I, Michael E. Wall, declare:

1. I am a member in good standing of the bar of this Court and am a senior attorney at petitioner Natural Resources Defense Council ("NRDC"). I serve as counsel for NRDC in this proceeding.

2. On August 15, 2005, NRDC filed a Freedom of Information Act ("FOIA") request with Respondent Environmental Protection Agency ("EPA"). EPA has subsequently released a number of documents to NRDC, in several sequential batches, in response to this August 15, 2005 FOIA request (hereinafter, the "Human Testing FOIA request"). EPA had some of the released documents delivered to me, directly, and had the remaining released documents delivered to other NRDC personnel. NRDC has maintained all records of these communications, including all documents released by EPA in response to the Human Testing FOIA request, in the course of its regularly conducted activities. I am familiar with these records.

3. The document attached as Exhibit C to this Declaration is a true and correct copy of a document EPA produced in response to NRDC's Human Testing FOIA request.

order the administrative record completed with the documents attached as Exhibits A-D to the accompanying Declaration.

September 28, 2006

Respectfully Submitted,

By: _____

Michael E. Wall
Aaron Colangelo
NATURAL RESOURCES DEFENSE COUNCIL
111 Sutter Street, 20th Floor
San Francisco, CA 94104
(415) 875-6100

Jan Hasselman
Patti Goldman
EARTHJUSTICE
705 Second Avenue, Suite 203
Seattle, WA 98104
(206) 343-7340

Shelley Davis
FARMWORKER JUSTICE FUND
1010 Vermont Ave., NW
Washington, DC 20005
(202) 783-2628

Counsel for Petitioners

expressly discuss the proposed Rule ("PR" or "Rule"), the "FY 2006 appropriations act" (*i.e.*, Section 201) that directed EPA to promulgate the Rule, and associated standards ("stds") or "guidelines" for "acceptance of human research," "exposure studies [with] humans," and "toxicity studies." These notes also describe how a pesticide company, Monsanto, may have "launder[ed]" a human testing study through a foreign university, *see* Wall Decl. Ex. D at 4 – evidence that bears on whether EPA's Rule complies with Section 201.[6] Because these notes reflect evidence before the Agency during the Human Testing Rulemaking, they are properly part of the administrative record.

III. CONCLUSION

Each of the above-referenced documents is plainly part of the administrative record to the Human Testing Rule. To assure that this Court can review the Rule on the "whole record," 5 U.S.C. § 706, rather than the incomplete set of materials selected by EPA, this Court should grant Petitioners' motion and

[6] Section 201 directed EPA to "not permit" the "use of pregnant women, infants and children as subjects" in "intentional dosing human toxicity studies for pesticides" – at all. 119 Stat. 531. Petitioners contend that EPA's rule, which restricts third-party research only if "intended" to be submitted or held for EPA, 71 Fed. Reg. 6174 (Feb. 6, 2006), violates Section 201 by, among other things, allowing the results of industry-funded human experiments to be laundered through journals or universities without direct submission to EPA. Document D suggests that EPA was aware such "laundering" occurs or may occur.

admission establishes that this document was considered in the rulemaking and constitutes part of the administrative record.[5]

C. EPA National Enforcement Investigations Center Memorandum Regarding "Review of the Proposed Rule: Protections for Test Subjects in Human Research" (Wall Decl., Ex. C)

Document C conveys comments from EPA's enforcement office "on the final Agency review draft" of the Human Testing Rule. *See* Wall Decl. Ex. C at 1. These comments are, by definition, part of the "evidence" and "proceedings" before EPA during the Rulemaking. *See* 28 U.S.C. § 2112(b); Fed. R. App. P. 16(a). The document is properly part of the rulemaking record.

D. EPA Notes Regarding Human Testing Rule and Briefing (Wall Decl. Ex. D)

Document D consists of handwritten notes from what EPA has described as "a staff briefing of Agency management related to EPA's development of a policy related to whether, and how, to use human studies in Agency decision making." *See* Wall Decl. ¶¶ 4-6 and Exs. D, E. The notes, dated less than ten days after EPA issued its proposed Human Testing Rule, *see* note 3, *supra*,

---

[5] This document also is relevant to EPA's challenge to Petitioners' standing. EPA's earlier motion to dismiss on standing grounds, which this Court denied without prejudice, claimed that the Human Testing Rule would not cause EPA to set higher pesticide exposure limits. Document B belies that contention by explaining how EPA intends to rely on human studies for the pesticide DDVP to raise the applicable exposure limit by 10 fold. *See* Wall Decl. Ex. B at 2.

promulgate the Human Testing Rule and set standards for that rule. In particular, Section 201 required EPA to issue a rule applicable to all intentional human dosing toxicity studies "for pesticides."

The guidance document sets forth an EPA interpretation of the statutory phrase "for pesticides" that is directly inconsistent with EPA's present interpretation, as memorialized in the Human Testing Rule. *Compare* Wall Decl. Ex. A1 at 15-16 *with* 71 Fed. Reg. 6163-64 (Feb. 6, 2006). Because this EPA guidance is part of the "evidence," "findings," and "proceedings," *see* 28 U.S.C. § 2112(b), Fed. R. App. P. 16(a), before EPA in its Human Testing Rulemaking, it is properly part of the administrative record.

B. EPA Draft "Fact Sheet" on Pesticide DDVP (Wall Decl., Ex. B)

Document B is an EPA-authored draft reference sheet that describes particular human toxicity studies and how EPA's reliance on those studies would allow EPA to set less protective human health standards. EPA has expressly acknowledged that this document, which was generated just two months before EPA issued its proposed Human Testing Rule, concerns "EPA's development of a policy related to whether, and how, to use human studies in Agency decision making" – *i.e.*, that it concerns the Agency's development of the Human Testing Rule. *See* Wall Decl. ¶¶ 4-6 and Exs. B, E and note 3, *supra*. EPA's own

under the Freedom of Information Act ("FOIA"), *see* Wall Decl. ¶¶2-6 (filed concurrently), falls well within the administrative record's scope.[3]

A. EPA Guidance for Implementing Section 201 of the Appropriations Act Regarding Intentional Dosing Human Toxicity Studies for Pesticides (Wall Decl., Exs. A1, A2)

Documents A1 and A2 include copies of a final EPA guidance memorandum that set forth EPA's then-interpretation of Section 201 of the Department of the Interior, Environment and Related Agencies Appropriations Act, 2006, § 201, Pub. L. 109-54, 119 Stat. 499, 532 ("Section 201"), as well as emails transmitting that memorandum to the relevant EPA offices. *See* Wall Decl. ¶¶ 4-6 and Exs. A1, A2, E.[4] Section 201 forms the principal basis for Petitioners' legal claims in this litigation; it is the statute that directed EPA to

---

[3] The documents at issue in this Motion were all generated by EPA during the timeframe of its Rulemaking. EPA announced its intention to pursue that rulemaking on February 8, 2005, issued a proposed rule on September 12, 2005, and published its final rule on February 6, 2006. *See* 70 Fed. Reg. 6661, 6666 (Feb. 8, 2005); 70 Fed. Reg. 53838 (Sept. 12, 2005); *and* 71 Fed. Reg. 6138 (Feb. 6, 2006). The five documents now at issue were created between June and September 2005. *See* Wall Decl. Exs. A1 and A2 (appendix 2 dated Sept. 30, 2005); Ex. B (July 22, 2005); Ex. C (June 28, 2005); Ex. D (Sept. 21, 2005).

[4] EPA originally withheld these documents and the documents described at Parts II.B and II.D, below, under FOIA. See Wall Decl. ¶¶ 4-6 and Exs. A1, A2, B, D and E. These documents were ultimately released by EPA after NRDC filed a FOIA lawsuit. *See NRDC v. OMB*, 05-CV-10594 (S.D.N.Y. 2005). The EPA descriptions of these documents cited here and at Parts II.B and II.D are taken from a privilege log EPA produced in support of its initial withholding decisions, before the Agency reversed course and released the documents. Relevant excerpts of that privilege log are attached at Wall Decl. Ex. E. *Id.*

"evidence" and "proceedings" before EPA on this matter. 28 U.S.C. § 2112(b); Fed. R. App. P. 16(a). Thus, "[t]he complete administrative record consists of all documents and materials directly or indirectly considered by the agency." *Bar MK Ranches v. Yuetter*, 994 F.2d 735, 739 (10th Cir. 1993); *see Dopico*, 687 F.2d at 654 (holding that the administrative record encompasses the agency's "informational base" at time of the disputed decision); *Walter O. Boswell Mem'l Hosp.*, 749 F.2d at 792 (holding that a reviewing court "should have before it neither more nor less information than did the agency when it made its decision"). The APA's "whole record" review standard assures judicial access to all material, favorable or not, before an agency during a rulemaking – and prevents an agency from withholding unfavorable materials. *See, e.g.*, *Dopico*, 687 F.2d at 654; *Walter O. Boswell Mem'l Hosp.*, 749 F.2d at 792; *see also United States v. Int'l Bhd. of Teamsters, AFL-CIO*, 156 F.3d 354, 363 (2nd Cir. 1998) (describing APA "whole record" review standard).[2]

The "whole record" before EPA during its Human Testing Rulemaking necessarily includes documents considered by EPA during that Rulemaking that bear on the Human Testing Rule's validity and effect. Each of the following documents, produced by EPA to petitioner Natural Resource Defense Council

---

[2] EPA waived any claim that the material is privileged when it consciously produced the subject documents to petitioner Natural Resources Defense Council under the Freedom of Information Act, 5 U.S.C. § 552.

I. INTRODUCTION

Petitioners respectfully move for an order completing the administrative record with five documents that were considered by EPA during the Human Testing Rulemaking, the subject of this litigation. 71 Fed. Reg. 6138 (Feb. 6, 2006); Petition for Review (February 23, 2006). The five documents include final EPA guidance on key statutory language concerning the scope of the Human Testing Rule and EPA commentary on the proposed Rule itself. These documents were before the Agency during its rulemaking, bear directly on Petitioners' legal claims, and are properly part of the administrative record under the Administrative Procedure Act's ("APA's) "whole record" review standard. 5 U.S.C. § 706.

II. ARGUMENT

In determining whether EPA's Human Testing Rule should be set aside under the APA, this Court must "review the whole record or those parts of it cited by a party."[1] 5 U.S.C. § 706; *see Dopico v. Goldschmidt*, 687 F.2d 644, 654 (2nd Cir. 1982); *Walter O. Boswell Mem'l Hosp. v. Heckler*, 749 F.2d 788, 792 (D.C. Cir. 1984). The "whole record" includes, among other things, not only the "findings" and "reports" on which the Human Testing Rule is based, but all

[1] Petitioners intend to cite the documents at issue in their merits briefing, subject to the outcome of this motion.

UNITED STATES COURT OF APPEALS
FOR THE SECOND CIRCUIT

NATURAL RESOURCES DEFENSE COUNCIL, INC., *et al.*	)	
Petitioners,	)	**No. 06-0820-ag (L)**
	)	No. 06-1895-ag (CON)
v.	)	No. 06-2149-ag (CON)
	)	No. 06-2360-ag (CON)
U.S. ENVIRONMENTAL PROTECTION AGENCY,	)	
Respondent.	)	

PETITIONERS' REPLY IN SUPPORT OF MOTION TO COMPLETE THE ADMINISTRATIVE RECORD

JAN HASSELMAN
PATTI GOLDMAN
Earthjustice
705 Second Avenue, Ste. 203
Seattle, WA 98104
Tel: (206) 343-7340

SHELLEY DAVIS
Farmworker Justice Fund
1010 Vermont Ave., NW, Ste. 915
Washington, DC 20005
Tel: (202) 783-2628

MICHAEL WALL
AARON COLANGELO
Natural Resources Defense Council
111 Sutter Street, 20th Floor
San Francisco, CA 94104
Tel: (415) 875-6100

Counsel for Petitioners

I. INTRODUCTION

The five documents that EPA refuses to put before this Court constitute "evidence[] and proceedings before the agency," 28 U.S.C. § 2112(b), during the Human Testing Rulemaking, and fit squarely within the broad, statutory definition of the administrative record on which review must proceed, 5 U.S.C. § 706. Although EPA claims it never considered three of these documents, uncontroverted evidence shows that EPA staff working on the Rule authored the documents, to address the Rule's subject, during the Rulemaking.

EPA's claim that some of the documents are "deliberative," and thus outside the record, mistakenly assumes that the qualified, common-law "deliberative process" privilege automatically trumps Congress' definition of the record, 28 U.S.C. § 2112(b), and the requirement that judicial review proceed on that "whole record," 5 U.S.C. § 706. EPA has, in any event, failed properly to invoke the deliberative process privilege here and also waived any privilege that might otherwise apply by publicly disclosing these documents. EPA should not be allowed selectively to exclude these public documents, which were before the Agency during the Human Testing Rulemaking, simply because they hurt its case. *Walter O. Boswell Mem'l Hosp. v. Heckler*, 749 F.2d 788, 792 (D.C. Cir. 1984) ("To review less than the full administrative record might allow a party to withhold evidence unfavorable to its case.")

II. ARGUMENT

A. EPA Cannot Retrospectively Redefine the "Whole Record" to Exclude Documents that Were Before It During the Rulemaking

The record on direct review of a rulemaking is statutorily defined to include all "evidence" and "proceedings" "before" the agency, 28 U.S.C. § 2112(b); Fed. R. App. P. 16(a); it normally encompasses all documents "directly or indirectly considered" during development of a rule. *Bar MK Ranches v. Yuetter*, 94 F.2d 735, 739 (10th Cir. 1993); *see also Dopico v. Goldschmidt*, 687 F.2d 644, 654 (2nd Cir. 1982). Here, uncontroverted evidence shows that the three documents EPA now claims it did not "consider" were in fact squarely before the Agency during the Human Testing Rulemaking. The Court should reject EPA's effort selectively to exclude these materials. *Dopico*, 687 F.2d at 654; *see also Walter O. Boswell Mem'l Hosp.*, 749 F.2d at 792. [1]

1. Documents A1 & A2 Were Before EPA in the Rulemaking

Documents A1 and A2 encompass a final "Internal OPP Guidance for Implementing the EPA FY 2006 Appropriations Act Provisions Regarding Acceptance, Consideration, and Reliance on Third-Party Intentional Dosing Human Toxicity Studies for Pesticides" (the "Guidance"). EPA's claim that this Guidance was not before EPA in the Rulemaking is perplexing, as the Guidance

[1] EPA offers no evidence to support its characterizations of most of the documents at issue. EPA's evidence on Document D is both irrelevant to the issues in the motion and inadmissible hearsay. EPA Opp., Ex. 1 at ¶ 5.

expressly addresses "What Studies Are Covered by the Appropriations Act," and in particular, the Appropriations Act's requirements pertaining to "*intentional dosing human toxicity studies for pesticides*" and a "*final rulemaking on this subject*." Wall Decl. (Sept. 28, 2006), Ex. A1 at 11 (emphasis in Guidance).

Moreover, contrary to EPA's claim, no Chinese Wall "separate[d]" the Guidance from development of the Rule. EPA Opp. at 7. The original draft of the Guidance was circulated by William Jordan, who described it as "defin[ing] key terms in the Appropriations Act." *See* Colangelo Decl., Ex. F at 2. Jordan was *the* EPA contact listed in the final Human Testing Rule, 71 Fed. Reg. 6138 (Feb. 6, 2006) (A1299[2]), and by his own admission "was assigned to develop the Rule," Jordan Decl. ¶ 1 (Oct. 11, 2006). EPA employee John Carley then forwarded the final Guidance to others, who he said should "share it widely." Wall Decl., Ex. A1 at 2. Carley was *the* lead EPA staffer sent to an Office of Management and Budget meeting with pesticide industry officials to discuss the Rule. EPA Revised Index of Administrative Record, Doc. No. 711 (EPA-HQ-OPP-2003-0132-664), *available at* www.regulations.gov; *see also* A401 (Doc. No. 711). Another EPA employee, Ray Kent, again forwarded the Guidance to others EPA employees, with a note he would "update this guidance as needed."

[2] References to "A[xxx]" are to the Appendix filed with Petitioners' brief.

Wall Decl., Ex. A2 at 1. Kent, like Carley and Jordan, was a member of EPA's "Appropriations Act Implementation Work Group." *Id.*, Ex. A1 at 10.

2. Document B Was Before EPA in the Rulemaking

Document B is a fact sheet that discusses the impact on human exposure standards if EPA used (and potential ethical problems with) a human study for the pesticide DDVP. This fact sheet was circulated on July 22, 2005, along with similar fact sheets on other pesticides. *See* Colangelo Decl., Ex. G. When EPA originally withheld these fact sheets under the Freedom of Information Act (FOIA), EPA asserted that they were prepared during development of a "final policy on the use of human studies." *Id.*, Ex. G at 1. Because that final policy *is* the Human Testing Rule, these documents are part of the record for that Rule.

If EPA's admission were not enough, the evidence also shows that John Carley – one of EPA's lead staffer on the Rule, *see supra*, at 3 – was also an author of Document B, *see* Colangelo Decl., Ex. G at 1; that Document B addressed how EPA might use human studies subject to the Rule, *see* Wall Decl., Ex. B; and that Document B described ethical problems, such as dosing young children, *id.*, that the Appropriations Act required the Rule to address, *see* 119 Stat. 532. Document B thus reflects "evidence" and "proceedings" "before" EPA during its Human Testing Rulemaking. 28 U.S.C. § 2112(b).

B. The Deliberative Process Privilege Does Not Preclude Judicial Consideration of Documents B, C, or D

1. The Administrative Record Does Not Automatically Exclude All Deliberative Documents

The deliberative process privilege is a "qualified, common law, executive privilege." *Landry v. FDIC*, 204 F.3d 1125, 1135 (D.C. Cir. 2000). As such, the privilege must be balanced against "the public's interest in honest, effective government." *Texaco Puerto Rico, Inc. v. Dep't. of Consumer Aff.*, 60 F.3d 867, 885 (1st Cir. 1995). In view of the requirement that judicial review occur on "neither more nor less" than the record that was before the agency, *Boswell*, 749 F.2d at 792, the privilege does not shield material (such as Documents B, C and D) that is both "germane to the decision and not duplicated elsewhere in the record." *Suffolk Cty. v. Sec'y of Interior*, 562 F.2d 1368, 1384 (2nd Cir. 1977).

It is telling that the incomplete record EPA has certified includes a number of documents that appear at least as "deliberative" as Documents B, C and D. For example, EPA chose to certify as part of its record an August 15, 2005 memorandum from the Department of Health and Human Services commenting on a draft notice of proposed rulemaking (EPA-HQ-OPP-2003-0132-0242); an internal EPA memorandum, predating EPA's publication of a proposed Rule, regarding the purported "consistency" of EPA's proposed Rule with the Nuremberg Code (EPA-HQ-OPP-2003-0132-0247); and an internal EPA draft of

the Human Testing Rule (EPA-HQ-OPP-2003-0132-0505).[3] EPA presumably certified these documents as part of the administrative record because they constitute "evidence" and "proceedings" before the Agency, notwithstanding their possible "deliberative" qualities. Documents B, C and D are properly part of the record for precisely the same reason. EPA should not be allowed selectively to exclude them because these *particular* documents are damaging in this litigation.

2. EPA Has Not Adequately Supported Its Invocation of the Deliberative Process Privilege

EPA has failed properly to invoke the deliberative process privilege. As courts have widely recognized, "[a]ssertion of the deliberative process privilege . . . requires a formal claim of privilege by the head of the department with control over the information," including "a description of the documents involved, a statement by the department head that she has reviewed the documents involved, and an assessment of the consequences of disclosure of the information." *Northrop Corp. v. McDonnell Douglas Corp.*, 751 F.2d 395, 405 n.11 (D.C. Cir. 1984); *accord, e.g.*, *Landry*, 200 F.3d at 1135; *United States v. O'Neill*, 619 F.2d 222, 225-26 (3d Cir. 1980); *In re Grand Jury Subpoena Dated Aug. 9, 2000*, 218 F. Supp.2d 544, 552 (S.D.N.Y. 2002); Paul F. Rothstein & Susan W. Crump, 1

[3] The first and third of these documents are available on EPA's electronic docket (EPA-HQ-OPP-20003-0132-___) at www.regulations.gov. Pursuant to 28 U.S.C. § 2112(b), Petitioners have requested EPA to produce the other document.

Fed. Testimonial Privileges § 5.12 (2d ed.) (collecting cases). EPA has submitted no such declaration or affidavit here.

Even EPA's authorities confirm that the "proper approach" would have been for the Agency first to "consider any document that might have influenced the agency's decision to be 'evidence'" before the agency, and hence presumptively part of the administrative record, and only *then* apply "any privilege that the agency properly claims." *National Courier Ass'n v. Bd. of Governors of Fed. Reserve Sys.*, 516 F.2d 1229, 1241-42 (D.C. Cir. 1975).[4] Here, however, EPA did not certify an administrative record that included document B, C, and D, and then withhold those documents under express claim of privilege. Instead, EPA simply omitted the documents from the certified record. Petitioners and the Court would never have known these documents existed had Petitioners not filed a Freedom of Information Act request and then sued EPA when it failed to respond. Wall Decl. ¶¶ 2, 4.

EPA's approach of silently excluding from the record documents that it contends are privileged would improperly allow an agency preemptively to withhold material it deems unfavorable without ever identifying that material to

[4] Petitioners do not seek to establish "some new record made initially in the reviewing court" by, for example, taking testimony of the defendant agency's officials. *Camp v. Pitts*, 411 U.S. 138, 139-40 (1973). Rather, Petitioners seek completion of "the administrative record already in existence," which *Camp* teaches is precisely the proper "focal point for judicial review." *Id.* at 142.

the Court or other litigants. Such an outcome is not only inconsistent with established deliberative process precedent, *see supra*, at 5-6, it is fundamentally incompatible with the very notion of "whole record" review. *See United States v. Int'l. Bhd. of Teamsters*, 864 F.2d 1225, 1230 (2nd Cir. 1989) (citing *Universal Camera Corp. v. NLRB*, 340 U.S. 474 (1951)) ("In considering the record, we examine all of the evidence, not just that supporting [the agency's] conclusion."); *Dopico,* 687 F.2d at 654 ("Determining what constitutes an agency's informational base is vital, for review must be based on the whole administrative record . . . ."). EPA's failure to identify the privileged materials and support that claim of privilege with an appropriate affidavit is fatal to its present defense.

3. EPA Has Waived Any Privilege Through Public Disclosure

An agency's voluntary public disclosure of "deliberative" documents waives the deliberative process privilege. *North Dakota v. Andrus*, 581 F.2d 177, 181-82 (8th Cir. 1978); *Mead Data Central, Inc. v. U.S. Dept. of Air Force*, 566 F.2d 242, 258 (D.C. Cir. 1977); *City of Virginia Beach v. U.S. Dep't. of Commerce*, 995 F.2d 1247, 1253 (4th Cir. 1993). This is because the privilege shields an agency's internal, pre-decisional deliberations from the "chilling" effect of *public* scrutiny. *See, e.g., NLRB v. Sears, Roebuck & Co.*, 421 U.S. 132, 150 (1975) (reasoning that "frank discussion . . . might be inhibited if the discussions were made public" and that "those who expect public dissemination

of their remarks may well temper candor"); *see also Lead Indus. Ass'n v. Occupational Safety & Health Admin.*, 610 F.2d 70, 82, 84 (2nd Cir. 1979). The deliberative process privilege simply does not shield material an agency has itself voluntarily *exposed* to public scrutiny. *See Andrus*, 581 F.2d at 179, 182 (rejecting claim that documents disclosed in unrelated litigation were privileged).

Documents B, C, and D are not privileged because EPA chose to disclose them to the public. *See* Pet. Mot. at 2-3; Wall Decl. ¶ 3, 6. EPA's claim that its deliberations would be dampened by disclosure of these same documents to the Court cannot be reconciled with EPA's public release. Wall Decl. ¶¶ 3, 6. Any privilege that otherwise might apply is, therefore, waived.[5]

EPA responds to this point by citing inapposite decisions and out-of-Circuit *dicta*. Many of EPA's cases concern litigants' efforts to discover documents (or take testimony) that had not previously been made public. *See, e.g., San Luis Obispo Mothers for Peace v. NRC*, 751 F.2d 1287, 1323-24 (D.C. Cir. 1984; *Checkosky v. SEC*, 23 F.3d 452, 489 (D.C. Cir. 1994). In such circumstances, judicial disclosure would presumably also have exposed the agencies' deliberations to *public* scrutiny. Here, by contrast, the public damage – if any –

[5] The inference of waiver is especially strong here because EPA's release of the documents represented an affirmative abandonment of the Agency's prior assertion of the deliberative process privilege under FOIA Exemption 5. *See* Wall Decl. ¶¶ 4-6 and Ex. E (privilege log); 5 U.S.C. § 552(b)(5) (incorporating litigation privileges, such as the deliberative process privilege).

has been done.[6] As for EPA's reliance on the plurality *dictum*[7] in *San Luis Obispo*, 751 F.2d at 1326, that decision's suggestion that judicial inquiry is more "worrisome" than public disclosure is not only inconsistent with the history of recent Washington scandals, it contravenes Congress' command that *all* evidence and proceedings before an agency be included in the administrative record for judicial review, not simply that evidence and proceedings that the Agency wishes to disclose to the court. 28 U.S.C. § 2112(b).

III. CONCLUSION

For these reasons, Petitioners' motion should be granted.

---

[6] EPA's citation to *PLMRS Narrowband v. FCC*, 182 F.3d 995 (D.C. Cir. 1999), is even less pertinent because that case did not discuss the scope of the administrative record, but instead held that the evidence at issue was insufficient to show the respondent's stated rationale was a pretext. *Id.* at 1001.

[7] The *San Luis Obispo* panel plurality declined to supplement the record with *non-public* agency meeting transcripts because the exceptions under which supplementation might have been permitted did not apply – *not* because judicial disclosure was more threatening than public disclosure. 789 F.2d at 212-13. On *en banc* review, *San Luis Obispo Mothers for Peace v. NRC*, 789 F.2d 26, 44 (D.C. Cir. 1986), a plurality of the full court affirmed that result without reiterating the panel plurality's *dictum* to which EPA cites. Judge Mikva, the *en banc* court's fifth vote, declined to adopt the "plurality's attempt to safeguard agency deliberations by an absolute judicial refusal to inspect [agency hearing] transcripts at the threshold of inquiry." 789 F.2d at 45.

October 23, 2006

Respectfully Submitted,

By: _____

Michael E. Wall
Aaron Colangelo
NATURAL RESOURCES DEFENSE COUNCIL
111 Sutter Street, 20th Floor
San Francisco, CA 94104
(415) 875-6100

Jan Hasselman
Patti Goldman
EARTHJUSTICE
705 Second Avenue, Suite 203
Seattle, WA 98104
(206) 343-7340

Shelley Davis
FARMWORKER JUSTICE FUND
1010 Vermont Ave., NW
Washington, DC 20005
(202) 783-2628

Counsel for Petitioners

DECLARATION OF AARON COLANGELO IN SUPPORT OF PETITIONERS' MOTION TO COMPLETE THE ADMINISTRATIVE RECORD

I, Aaron Colangelo, declare:

1. I am a member in good standing of the bar of this Court and am a senior attorney at petitioner Natural Resources Defense Council ("NRDC"). I serve as counsel for NRDC in this proceeding.

2. On August 15, 2005, NRDC filed a Freedom of Information Act ("FOIA") request with Respondent Environmental Protection Agency ("EPA"). EPA has subsequently released a number of documents to NRDC, in several sequential batches, in response to this August 15, 2005 FOIA request (hereinafter, the "Human Testing FOIA request"). EPA had some of the released documents delivered to me, directly, and had the remaining released documents delivered to other NRDC personnel. NRDC has maintained all records of these communications, including all documents released by EPA in response to the Human Testing FOIA request, in the course of its regularly conducted activities. I am familiar with these records.

3. The documents attached as Exhibits F and G to this Declaration are true and correct copies of documents EPA produced in response to the Human Testing FOIA Request, identified by document tracking numbers 1310 (Exhibit F) and 1125 (Exhibit G).

I declare under penalty of perjury that the foregoing is true and correct to the best of my knowledge, information, and belief.

Dated: Washington, District of Columbia
October 23, 2006

Aaron Colangelo

Exhibit F

Document Log

Review Status = Pending
Exemption/Privilege = Ex. 5 -- Deliberative Process Privilege

Review Status	● Pending	○ Complete

From	To
William Jordan/DC/USEPA/US	
CC	**BCC**

Subject	Date/Time	Document Type
Re: Guiance on the Appropiations Act Human Studies Provision	09/28/2005	Email w/o attachment

Tracking Number	Pages	Exemption/Privilege
EPA-1310	2	Ex. 5 -- Deliberative Process Privilege

Description

Exemption 5: Effect of Appropriations legislation. The withheld information in this document concerns EPA's actions in response to the promulgation of legislation discontinuing the Agency's reliance on human studies. In August 2005, the President signed an Appropriations Act that discontinued reliance on third-party, intentional human dosing toxicity studies in its decision-making under FIFRA and FFDCA until the Administrator issues a final rulemaking on this subject. The Act also mandated that the rule (1) shall not permit the use of pregnant women, infants or children as subjects; (2) shall be consistent with the principles proposed in the 2004 report of the National Academy of Sciences on intentional human dosing and the principles of the Nuremberg Code with respect to human experimentation; and (3) shall establish an independent Human Subjects Review Board. The withheld information in this document concerns a draft internal guidance document providing recommended actions and considerations for implementing the Appropriations Act. The discussions are predecisional and deliberative because the Agency's was still considering the issue at the time the document was created. The withheld information does not reflect final Agency action. Release would have a chilling effect on Agency decision-making and on open and frank discussions and consultations among EPA staff and managers. In addition, these discussions contained the Agency's consideration of options and represent attorney-client privileged communications. The discussions contain confidential discussion between EPA staff and EPA attorney's related to the potential Agency actions in response to the court's opinion. The communications are privileged because they contain discussions in which EPA staff sought legal advice from EPA attorneys. Release of this material would allow public scrutiny of sensitive, confidential communications between the attorneys and clients. The withheld information was not circulated outside of the federal government

Release/Withhold Status	Explain Release/Withhold Status
Release in Part/Withhold in Part	Document is predecisional and deliberative, because the project was on-going when the document was drafted, the drafter lacked decision-making authority. Release would have a chilling effect on Agency decision-making processes and cause public confusion about the reason for an Agency decision.

Optional Notational Fields

Open Notation 1	Open Notation 2	Notation 1	Alpha Notation 2
		None	None

Document Body

William Jordan/DC/USEPA/US
09/28/2005 11:00 AM

To: William Sette/DC/USEPA/US@EPA

cc: Aubrey Miller/EPR/R8/USEPA/US@EPA, Bruce Rodan/DC/USEPA/US@EPA, Cary Secrest/DC/USEPA/US@EPA, Charlotte Bertrand/DC/USEPA/US@EPA, Dennis Utterback/DC/USEPA/US@EPA, Diana-M Wong/DC/USEPA/US@EPA, Elizabeth Doyle/DC/USEPA/US@EPA, Ernest Falke/DC/USEPA/US@EPA, Gregory Miller/DC/USEPA/US@EPA, Hal Zenick/RTP/USEPA/US@EPA, Iris Camacho/DC/USEPA/US@EPA, John Carley/DC/USEPA/US@EPA, Joyce Jatko/DC/USEPA/US@EPA, Karen Martin/RTP/USEPA/US@EPA, Keith Matthews/DC/USEPA/US@EPA, Kent Thomas/RTP/USEPA/US@EPA, Kevin Teichman/DC/USEPA/US@EPA, Larry Cupitt/RTP/USEPA/US@EPA, Lee Tyner/DC/USEPA/US@EPA, Margaret Jones/R5/USEPA/US@EPA, Maryann Suero/R5/USEPA/US@EPA, Michael Firestone/DC/USEPA/US@EPA, Michele Burgess/DC/USEPA/US@EPA, Nicole Paquette/DC/USEPA/US@EPA, Peter Preuss/DC/USEPA/US@EPA, Philip Ross/DC/USEPA/US@EPA, Ray Kent/DC/USEPA/US@EPA, Richard Hermann/RTP/USEPA/US@EPA, Roger Cortesi/DC/USEPA/US@EPA, Suhair Shallal/DC/USEPA/US@EPA, Tanya Maslak/DC/USEPA/US@EPA, William Sette/DC/USEPA/US@EPA

bcc:

Subject: Re: Guidance on the Appropriations Act Human Studies Provision

As you should know, the FY 2006 Appropriations Act for EPA contains a provision prohibiting use of funds made available under that law to conduct certain kinds of human research, as well as to accept, consider, and rely on third-party, intentional dosing, human toxicity studies for pesticides. This provision remains in force until EPA issues a final human studies rule.

OPP is developing a guidance document that defines key terms in the Appropriations Act and explains what types of actions EPA is (and is not) allowed to take. See the attached file.

Guidance – BJ 9-28-05 clean.doc

We recommend that other offices in EPA consider developing guidance to address how your organizations will implement this statutory requirement.

Since the prohibitions in the Appropriations Act become effective on October 1, 2005, OPP will issue this guidance very soon. Therefore, I NEED ALL COMMENTS BY NOON ON FRIDAY SEPTEMBER 30.

There are several pieces of the guidance that are likely to be of special interest to organizations outside OPP.

Feel free to call or e-mail if you have any questions.

Thanks,

Bill

William L. Jordan
Senior Policy Adviser
Office of Pesticide Programs -- Mail code 7501C
U. S. Environmental Protection Agency
1200 Pennsylvania Avenue, NW
Washington, DC 20460
(703) 305-1049 (voice)
(703) 308-4776 (fax)

Exhibit G

Document Log

Review Status = Pending
Exemption/Privilege = Ex. 5 -- Deliberative Process Privilege

Review Status	● Pending	○ Complete

From	To
Linda Murray/DC/USEPA/US	Margie Fehrenbach/DC/USEPA/US@EPA
CC	**BCC**

Subject	Date/Time	Document Type
the 'facts' as 'we' understand them 2day!	07/22/2005 04:59 PM	Email w/ attachment

Tracking Number	Pages	Exemption/Privilege
EPA-1125		Ex. 5 -- Deliberative Process Privilege

Description

Exemption 5: Human Studies Briefing
The withheld information in this document concerns a staff briefing of Agency management related to EPA's development of a policy related to whether, and how, to use human studies in Agency decision making. In December 2001, EPA (1) issued a press release stating that, among other things, while the NAS studied the issue, third-party intentional dosing studies conducted for the purpose of identifying or quantifying toxic effects would not be considered or relied on by the Agency in its regulatory actions, unless consideration of such data were legally required or necessary to protect public health; and (2) asked the NAS to advise the Agency on the many difficult scientific and ethical issues associated with the consideration of such human studies. The withheld information was generated for internal discussion as part of the Agency's process in determining the Agency's final policy on the issue. The document contains information discussed by staff for presentation to management for consideration and updates to management on staff progress on action items related to the development of the Agency policy. The withheld information is predecisional because it was generated prior to the Agency's final policy on the use of human studies. The withheld information is deliberative because it contains options being considered by staff and management in developing the Agency's policy. Release would have a chilling effect on Agency decision-making and on open and frank discussions and consultations among EPA staff and managers. These discussions also contain confidential communications between Agency staff and the Agency's attorneys in which the Agency's staff sought legal advice. Release of this material would allow public scrutiny of sensitive, confidential communications between the attorneys and clients. The withheld information was not circulated outside of the federal government.

Release/Withhold Status	Explain Release/Withhold Status
Release in Part/Withhold in Part	

Optional Notational Fields

Open Notation 1	Open Notation 2	Notation 1	Alpha Notation 2
		None	None

Document Body

Margie,

Here are the 'fact sheets' (per Susie's request) for Aldicarb, AZM, Carbofuran, DDVP and MITC -- which now
incorporate John Carley's ethics reviews re-writes AND HED's revisions.

Soooooooo, speaking for SRRD, HED and John C... we believe we are 'done' with these!
(and, don't burst our bubble either!!!)

Aldicarb Human Study Fact Sheet.22 July 2005..doc

AZM-Human Studies Fact Sheet.22 July 2005..doc

Carbofuran-Human Studies Fact Sheet.22 July 2005..doc

DDVP-Human Studies Fact Sheet.22 July 2005.DOC

MITC-Human Studies Fact Sheet July 22..doc

Here also is our most recent version of the table prepared in response to Susie's "Defense" request (e-note to Jim) that
includes the projected dates for upcoming rereg/tolerance reassessment actions/activities that involve intentional
exposure human tox studies...

Projected Public Release Schedule for HS Chems.22 July 2005.rtf

Linda Keola P. Murray ("Pineapple")
Special Assistant to the Director
Special Review and Reregistration Division (7508C)
Office of Pesticide Programs; OPPTS/U.S. EPA
phone: 703-305-5401
fax: 703-308-8005
email: Murray.Linda@epa.gov
mailing address: U.S. Environmental Protection Agency
Ariel Rios Building (7508C)
1200 Pennsylvania Avenue

Washington, DC 20460
office/deliveries location: 1801 South Bell Street
Crystal Mall # 2 (Rm 604-N)
Arlington, VA 22202

Aldicarb [7/22/05 @ 12:00 PM]

Protecting Human Health and the Environment

EPA meets its responsibilities for protecting public health and the environment by collecting and reviewing the best available scientific information to understand how air and water pollutants, pesticides, hazardous wastes, industrial chemicals, and other environmental substances may affect human health and the world we live in. The Agency typically reaches its regulatory decisions by considering a wide range of information about each substance including toxicity - its potential to cause harm, and through exposure - how and at what levels people may be exposed to the substance. By combining information on toxicity with estimates of exposure, EPA can assess the risk posed by a substance, and decide whether the amount of it released into the environment needs to be regulated.

Human Data Submitted to the Agency for Aldicarb

In assessing the potential toxicity of aldicarb to humans, EPA reviewed data from multiple scientific studies and used a "weight of evidence" approach. Specifically, the Agency looked at data from all available types of animal and human toxicity studies and carefully examined the scientific strengths and weaknesses of each study. EPA then considered the database and made a judgment based upon the "weight of evidence." The Agency does not automatically give controlling weight to one type of study or tally the number of studies. Instead, the "weight of evidence" judgment involves evaluating the quality and robustness of each individual study, giving greater weight to better run studies, and then looking across all of the studies to decide what the preponderance of the data shows.

In the case of aldicarb, the Agency reviewed one study using human subjects- a single oral dose study conducted by Inveresk Research International and BCG Ltd. in 1992. The study was designed to investigate cholinesterase activity following a single oral dose of aldicarb. A total of 38 men and 9 women took part in the study. Following an overnight fast, subjects were dosed with aldicarb or placebo in orange juice at breakfast. Cholinesterase activity was monitored hourly for the first 6 hours post dose and at 24 hours post dose. The study consisted of several phases/sessions such that all subjects were not dosed during the same time frame. While the Agency has not made any final risk assessment decisions, this study was considered in the preliminary risk assessment.

Aldicarb Acute Toxicity Study

The aldicarb oral acute human toxicity study is valuable to EPA. Effects were observed at common dose levels in both the animal and human studies. Although the Agency relied on animal data (in young rats) to establish a toxicity endpoint (effect of concern), the safety factor that is usually applied when only animal studies are used was able to be reduced while still being protective of human health.

Ethics Review

In a recent policy statement published in the Federal Register, the Agency announced that "EPA will continue to generally accept scientifically valid studies unless there is clear evidence that the conduct of those studies was fundamentally unethical (e.g., the studies were intended to seriously harm participants or failed to obtain informed consent), or was significantly deficient relative to the ethical standards prevailing at the time the study was conducted. The Agency notes that this approach is consistent with Recommendation 5-7 of the February 2004, NAS report." 70 Fed. Reg. 6661, February 8, 2005. The human study identified above was reviewed under this standard, and the complete ethics review is available in the docket. This review concluded that there was no clear evidence that the study was either fundamentally unethical or significantly deficient relative to the ethical standards prevailing at the time it was conducted, and thus the data from this study may be considered in the Agency's assessment. Nonetheless, when compared to contemporary ethical standards, the following ethical concerns about the study were identified:

- The informed consent materials misleadingly characterize aldicarb as a drug, and are significantly incomplete with respect to the risks to the subjects.
- There is suggestive evidence that the investigators did not follow through on their commitment to exclude all but post-menopausal or surgically sterile women.

AZM (Draft 7/22/05; 12:00 pm)

Protecting Human Health and the Environment

EPA meets its responsibilities for protecting public health and the environment by collecting and reviewing the best available scientific information to understand how air and water pollutants, pesticides, hazardous wastes, industrial chemicals, and other environmental substances may affect human health and the world we live in. The Agency typically reaches its regulatory decisions by considering a wide range of information about each substance including toxicity -- its potential to cause harm, and through exposure -- how and at what levels people may be exposed to the substance. By combining information on toxicity with estimates of exposure, EPA can assess the risk posed by a substance, and decide whether the amount of it released into the environment needs to be regulated.

Human Studies Submitted to the Agency for AZM (Azinphos-Methyl)

In assessing the potential toxicity of AZM to humans, EPA reviewed data from multiple scientific studies and used a "weight of evidence" approach. Specifically, the Agency looked at data from all available types of animal and human toxicity studies and carefully examined the scientific strengths and weaknesses of each study. EPA then considered the database and made a judgment based upon the "weight of evidence." The Agency does not automatically give controlling weight to one type of study or tally the number of studies yielding a particular result and simply rely on the outcome with the largest number of studies. Instead the "weight of evidence" judgment involves evaluating the quality and robustness of each individual study, giving greater weight to better run studies, and then looking across all of the studies to decide what the preponderance of the data shows.

In the case of AZM, the animal testing database is complete. An IRED (Interim Reregistration Eligibility Decision) was issued in October, 2001, phasing out many uses based upon concerns for workers and the environment. Several critical uses were retained, pending development of crop specific monitoring and other data. Some of the remaining uses are scheduled for phase-out by the end of 2005. The remaining critical uses are scheduled for re-evaluation, and EPA intends to make a decision on the continued use of AZM for these remaining uses by the end of 2005. In addition to the required data with laboratory animals, three studies using human subjects are available for EPA review. The Agency has not yet decided whether any of these studies with human subjects will be used in the reevaluation of the remaining uses of AZM. The human studies available for AZM include:

1. A single dose oral study, sponsored by the registrant Bayer, was conducted in 1998 at Inveresk Clinical Research in Scotland, with 50 adult human subjects, to establish a no observed adverse effect level (NOAEL) for cholinesterase inhibition. The study was well designed sound and ethically acceptable.

Use of the human study would lower the estimated acute dietary risk by approximately 10-fold.

In the Agency's IRED for AZM that was completed in 2001, the acute dietary risk was not of concern using animal data. The acute study with human subjects increases our confidence that acute dietary exposure was not underestimated in our 2001 assessment.

2. A repeat dose oral study, sponsored by the registrant Bayer, was conducted in 1999 at Inveresk Clinical Research in Scotland, with 12 adult male volunteers. The study was designed to determine if a single dose for 28 consecutive days could be established as a NOAEL for cholinesterase inhibition. The study was well designed, scientifically sound and ethically acceptable.

The repeat dose study can be used for both the short and intermediate term occupational risk assessments and would result in the estimated occupational risk being significantly less than calculated with the animal data.

3. A dermal absorption study, sponsored by Bayer, was conducted in 1999 in the Netherlands, with 18 adult males. Radiolabelled AZM was applied to the skin on the forearms of the subjects for 8 hours at 3 different dose levels with six subjects being dosed at each dose level. The study was well designed and ethically acceptable.

The metabolism study with human subjects demonstrated a wide range of dermal absorption ranging from as low as 11% to as high as 51%, but average values were from 21.89% to 29.32%. A factor of 42% based on animal data was already being used for dermal absorption of AZM. The study with human subjects confirms that dermal absorption was not underestimated in the previous AZM assessment.

Ethics Review

In a recent policy statement published in the Federal Register, the Agency announced that "EPA will continue to generally accept scientifically valid studies unless there is clear evidence that the conduct of those studies was fundamentally unethical (e.g., the studies were intended to seriously harm participants or failed to obtain informed consent), or was significantly deficient relative to the ethical standards prevailing at the time the study was conducted. The Agency notes that this approach is consistent with Recommendation ~~5~~ 7 of the February 2004, NAS report." 70 Fed. Reg. 6661, February 8, 2005. The human studies identified above were reviewed under this standard, and the complete ethics reviews are available in the docket. These reviews concluded that there was no clear evidence that the studies were either fundamentally unethical or significantly deficient relative to the ethical standards prevailing at the time they were conducted, and thus the data from these studies may be considered in the Agency's assessment. Nonetheless, when compared to contemporary ethical standards, the following ethical concerns about each study were identified:

Single and repeated-dose oral studies:

- Consent agreement is between subjects and an unidentified "supervising doctor" and "company"

- Subject information does not address benefits of the research or their distribution, or identify the sponsor of the research
- Ethics committee oversight is incompletely documented

Metabolism study:

- Subject information does not address benefits of the research or their distribution
- Consent agreement uses the threat of "fines" and withholding of compensation to enforce discipline

Carbofuran [22 July 2005 @ 12:00 PM]

Protecting Human Health and the Environment

EPA meets its responsibility for protecting public health and the environment by collecting and reviewing the best available scientific information to understand how air and water pollutants, pesticides, hazardous wastes, industrial chemicals, and other environmental substances may affect human health and the world we live in. The Agency typically reaches its regulatory decisions by considering a wide range of information about each substance including toxicity -- its potential to cause harm, and through exposure -- how and at what levels people may be exposed to the substance. By combining information on toxicity with estimates of exposure, EPA can assess the risk posed by a substance, and decide whether the amount of it released into the environment needs to be regulated.

Human Studies Submitted to the Agency for Carbofuran

In assessing the potential toxicity of carbofuran to humans, EPA considered data from multiple scientific studies and used a "weight of evidence" approach. Specifically, the Agency looked at data from all available types of animal and human toxicity studies and carefully examined the scientific strengths and weaknesses of each study. EPA then considered the full database and made a judgment based upon the "weight of evidence". The Agency did not automatically give controlling weight to one type of study or tally the number of studies yielding a particular result and simply rely on the outcome with the largest number of studies. Instead the "weight of evidence" judgment involves evaluating the quality and robustness of each individual study, giving greater weight to better run studies, and then looking across all of the studies to decide what the preponderance of the data shows.

Although human studies were reviewed for the carbofuran preliminary risk assessment, none were used. A 1976 human oral study and 1977 and 1978 human dermal studies were examined but none were found useful for risk assessment purposes due to serious deficiencies including: dosing errors, missing clinical data, too few subjects. These studies were also not useful for risk assessment purposes due to technical problems, for example the use of a nonspecific substrate (the material on which an enzyme works) for evaluation of red blood cell cholinesterase (the enzyme that breaks down and inactivates a chemical transmitter in the central nervous system known as acetylcholine).

The higher quality and better-designed and conducted chronic animal study was deemed to be more suitable for risk assessment purposes than the human oral study.

DDVP (Draft 7/22/05; 12:00 PM)

Protecting Human Health and the Environment

EPA meets its responsibilities for protecting public health and the environment by collecting and reviewing the best available scientific information to understand how air and water pollutants, pesticides, hazardous wastes, industrial chemicals, and other environmental substances may affect human health and the world we live in. The Agency typically reaches its regulatory decisions by considering a wide range of information about each substance including toxicity -- its potential to cause harm, and through exposure -- how and at what levels people may be exposed to the substance. By combining information on toxicity with estimates of exposure, EPA can assess the risk posed by a substance, and decide whether the amount of it released into the environment needs to be regulated.

Human Studies Submitted to the Agency for Dichlorvos (DDVP)

In assessing the potential toxicity of DDVP to humans, EPA reviewed data from multiple scientific studies and used a "weight of evidence" approach. Specifically, the Agency looked at data from all available types of animal and human toxicity studies and carefully examined the scientific strengths and weaknesses of each study. EPA then considered the database and made a judgment based upon the "weight of evidence." The Agency does not automatically give controlling weight to one type of study or tally the number of studies yielding a particular result and simply rely on the outcome with the largest number of studies. Instead the "weight of evidence" judgment involves evaluating the quality and robustness of each individual study, giving greater weight to better run studies, and then looking across all of the studies to decide what the preponderance of the data shows.

In the case of DDVP, while the Agency has not made any final risk assessment decision, 2 human studies were considered in the revised risk assessment. The first study was a 1997 repeated dose oral study in which male volunteers were administered DDVP daily for 21 days to determine the effects of DDVP exposure on the nervous system. Specifically, researchers were attempting to monitor the red blood cell (RBC) levels of cholinesterase (ChE), an enzyme which is critical to the proper functioning of the nervous system. Suppressed cholinesterase levels can result in dizziness, nausea, trembling, breathing difficulty, and in extreme cases, convulsions and death. In this study, cholinesterase activity was monitored 8 times during the 21-day dosing period, and one time during the week following dosing. The doses where effects were seen in this study were consistent with available toxicity studies performed on rats. As compared to animal data alone, use of the data from this human study to assess residential and occupational risks results in about a 3-fold increase in the amount of DDVP exposure deemed acceptable for the protection of human health.

The second human study used in the revised DDVP risk assessment was a 1967 residential exposure study ("Arizona II study"). In that study, DDVP impregnated resin strips were studied in a residential setting in Tucson, Arizona. There were 64 human subjects from 15 families, including 29 adults and 35 children. Strips were placed in the homes at the rate of one strip per 1000 cu feet (the rate approved on the registered pesticide label). Atmospheric concentrations of DDVP were measured throughout the study. All participants received thorough medical evaluations including

plasma and RBC ChE determinations, clinical chemistry evaluations, and physician evaluations. All complaints and symptoms were also recorded. In 2002 the original data from this exposure study was re-analyzed to estimate the effects of long-term inhalation exposure at various concentrations on the exposed subjects. This re-analysis involved no additional exposures of any human subjects to DDVP. As with the repeated dose study referenced above, the results from this human study were consistent with those from a two-year rat inhalation study. Employing this study in the risk assessment would allow about a 10-fold increase in the amount of DDVP exposure considered acceptable for the protection of human health

Ethics Review

In a recent policy statement published in the Federal Register, the Agency announced that "EPA will continue to generally accept scientifically valid studies unless there is clear evidence that the conduct of those studies was fundamentally unethical (e.g., the studies were intended to seriously harm participants or failed to obtain informed consent), or was significantly deficient relative to the ethical standards prevailing at the time the study was conducted. The Agency notes that this approach is consistent with Recommendation 5-7 of the February 2004, NAS report." 70 Fed. Reg. 6661, February 8, 2005. The human studies identified above were reviewed under this standard, and the complete ethics reviews are available in the docket. These reviews concluded that there was no clear evidence that the studies were either fundamentally unethical or significantly deficient relative to the ethical standards prevailing at the time they were conducted, and thus the data from these studies may be considered in the Agency's assessment. Nonetheless, when compared to contemporary ethical standards, the following ethical concerns about each study were identified:

21-day repeated dose study:

- The absence of documentation supporting the assertions of ethical conduct makes it very difficult to judge the credibility of those assertions. It is quite unusual for studies from this period to contain so little documentation of ethical factors. Deficient documentation to support the assertions of informed consent and ethical oversight does not in itself provide evidence that the ethical conduct of this study was substantively deficient relative to standards prevailing when it was conducted.

The residential exposure study ("Arizona II"):

- Extremely limited information about ethical factors (not unusual for studies from this period.)
- Exposure of whole families, including young children

MITC (Draft 7/22/05; 12:00 PM)

Protecting Human Health and the Environment

EPA meets its responsibilities for protecting public health and the environment by collecting and reviewing the best available scientific information to understand how air and water pollutants, pesticides, hazardous wastes, industrial chemicals, and other environmental substances may affect human health and the world we live in. The Agency typically reaches its regulatory decisions by considering a wide range of information about each substance including toxicity -- its potential to cause harm, and through exposure -- how and at what levels people may be exposed to the substance. By combining information on toxicity with estimates of exposure, EPA can assess the risk posed by a substance, and decide whether the amount of it released into the environment needs to be regulated.

Human Studies Submitted to the Agency for MITC (Methyl Isothiocyanate)

MITC is generated when dazomet, metam sodium, and the related chemical metam potassium (other pesticide chemicals) are used as soil fumigants. In assessing the potential toxicity of MITC to humans, EPA reviewed data from multiple scientific studies and used a "weight of evidence" approach. Specifically, the Agency looked at data from all available types of animal and human toxicity studies and carefully examined the scientific strengths and weaknesses of each study. EPA then considered the database and made a judgment based upon the "weight of evidence." The Agency does not automatically give controlling weight to one type of study or tally the number of studies yielding a particular result and simply rely on the outcome with the largest number of studies. Instead the "weight of evidence" judgment involves evaluating the quality and robustness of each individual study, giving greater weight to better run studies, and then looking across all of the studies to decide what the preponderance of the data shows.

In the case of MITC, the Agency has a limited database available to review. The Agency reviewed one eye irritation human study that supported a tougher exposure limit than the animal laboratory tests would. This study was performed in 1994-1995 at the School of Medicine, University of California, Davis. It was designed to determine the concentrations of MITC vapor that would produce no observable irritation responses in the eyes of normal, human volunteer test subjects. Thirty-three healthy males and females wore goggles into which air with measured concentrations of MITC was routed, and exposure continued for durations from a few minutes to 8 hours. The effects measured included subjective judgments of irritation, blink rate, tearing and visual acuity. EPA regards these effects as a surrogate for respiratory effects (e.g., lung, nasal). EPA determined that the study appears to have been in compliance with scientific and ethical standards in place at the time it was performed (an approach recommended by the National Academies of Science). While the Agency has not made any final risk assessment decision, this study was considered in the preliminary risk assessment.

A second human study (an odor threshold study) was conducted in 1994 by the same researcher and submitted to EPA in support of MITC. The Agency does not intend to use the odor threshold study

because it did not provide information useful for the risk assessment and it has significant ethical deficiencies.

MITC Eye Irritation Study

The MITC eye irritation study is valuable to EPA. This study using human subjects shows that humans are the most sensitive species in their response to MITC, which can cause adverse effects to people at exposure levels one-fourth the lowest level causing adverse effects in test animals. The MITC eye irritation study thus justifies stronger regulatory actions to protect public health. Using animal tests alone could lead EPA to allow four times as much MITC exposure as the Agency thinks would be safe. Using the MITC study, therefore, enables EPA to be more protective in regulating bystander exposure.

Some stakeholders have noted that EPA normally would not regulate a pesticide on the basis of acute eye irritation. The Agency usually would handle this type of risk concern on a product-specific level. This is true; however, in assessing acute active ingredient chemical risks, the Agency usually is focused on acute worker risks of concern, which can be addressed by requiring the use of protective eyewear. The soil fumigants are different in that acute eye irritation risks to bystanders are of concern, as borne out by a number of incidents in communities where the fumigants have been used and have moved off treated fields, causing eye irritation and more serious health effects among bystanders. Requiring use of protective eyewear is not a practical mitigation measure to address bystander risks. In this situation, therefore, EPA believes that it would be appropriate and protective to use the eye irritation effect found in this human study to protect bystanders from risks associated with exposure to MITC.

Ethics Review

In a recent policy statement published in the Federal Register, the Agency announced that "EPA will continue to generally accept scientifically valid studies unless there is clear evidence that the conduct of those studies was fundamentally unethical (e.g., the studies were intended to seriously harm participants or failed to obtain informed consent), or was significantly deficient relative to the ethical standards prevailing at the time the study was conducted. The Agency notes that this approach is consistent with Recommendation 5-7 of the February 2004, NAS report." 70 Fed. Reg. 6661, February 8, 2005. The human eye irritation study identified above was reviewed under this standard, and the complete ethics review is available in the docket. This review concluded that there was no clear evidence that the study was either fundamentally unethical or significantly deficient relative to the ethical standards prevailing at the time it was conducted, and thus the data from this study may be considered in the Agency's assessment. Nonetheless, when compared to contemporary ethical standards, the following ethical concerns about the study were identified:

- documentation of risk reduction and societal benefits is weak
- There is a possibility of subtly coercive recruitment of the investigator's students

Projected Dates for Upcoming Reregistration/Tolerance Reassessment Actions/Activities That Involve Intentional Exposure Human Toxicity Studies

as of July 22, 2005

Chemical	Error Correction Review	Anticipated Public Release (Phase 3 or 5)	Anticipated Decision Date
Amitraz			
Aldicarb			
Ethephon			
Malathion			
Carbofuran			
AZM (Azinphos Methyl)			
DDVP (Dichlorvos)			
Chloropicrin			
Metam Sodium/MITC			
Dazomet/MITC			
Dimethoate			
Oxytetracycline			

UNITED STATES COURT OF APPEALS
FOR THE SECOND CIRCUIT

NATURAL RESOURCES DEFENSE COUNCIL	)	
Petitioner,	)	**No. 06-0820-ag (L)** and consolidated petitions
v.	)	Case No. 06-1895-ag (CON)
	)	Case No. 06-2149-ag (CON)
	)	Case No. 06-2360-ag (CON)
U.S. ENVIRONMENTAL PROTECTION AGENCY	)	
Respondent.	)	

RESPONDENT EPA'S OPPOSITION TO PETITIONERS' MOTION TO COMPLETE THE ADMINISTRATIVE RECORD

I. INTRODUCTION

Petitioners challenge a rule titled "Protections for Subjects in Human Research" (the "Research Rule"), which significantly strengthens and expands the protections for subjects of human research when such studies are intended for submission to the United States Environmental Protection Agency ("EPA") under the Federal Food, Drug, and Cosmetic Act ("FFDCA") and the Federal Insecticide, Fungicide and Rodenticide Act ("FIFRA"). EPA filed a revised certified index to the administrative record for the Research Rule on June 23, 2006. The certified index contains over 700 documents considered by EPA as part of its rulemaking

process.

The five documents Petitioners seek to add to the administrative record should not be included in the record because they either were not considered by EPA in connection with the Research Rule or are deliberative in nature, or both. Petitioners' Documents A1 and A2 are internal guidance prepared to assist EPA staff in complying with a provision of the 2006 Appropriations Act that prohibited EPA's use of human research studies prior to promulgation of the Research Rule. These guidance documents were not considered in development of the Research Rule. Document B, a draft fact sheet on the chemical DDVP, is a preliminary document that relates to risk assessments relevant to a separate EPA decisionmaking process regarding the chemical DDVP, and not the Research Rule.

Documents B, C and D are deliberative, internal communications between EPA personnel that do not form part of the record upon which EPA bases its action. As discussed below, in order to ensure open communication and the free exchange of ideas and opinions through an agency's decisionmaking process, and to prevent placing a chill on such communications, deliberative documents should be excluded from the record for judicial review. Courts have routinely recognized that the rationale for this general rule applies to all deliberative documents, even if publicly available. Document B is a draft staff-level analysis of the impact of

using human studies on the DDVP risk assessment, intended to inform management in the decisionmaking process on DDVP. Document C is a deliberative memorandum prepared by an EPA employee reflecting internal, staff-level comments. Document D is handwritten notes reflecting a briefing of a manager on the status of the rulemaking. Documents B, C and D reflect tentative EPA positions embodied in draft or preliminary documents that are not properly included in the administrative record.

II. BACKGROUND

A. Regulation of Pesticides Under the FFDCA and FIFRA

FFDCA Section 408(b)(1) authorizes EPA to establish, by regulation, "tolerances" that set the maximum permissible levels of pesticide residues in or on foods. 21 U.S.C. § 346a(b)(1). EPA is to establish regulations setting a tolerance for a pesticide residue or, in appropriate cases, an exemption from the tolerance requirement, only if EPA determines that the tolerance or exemption is "safe." FFDCA section 408(b)(2)(A)(i), 21 U.S.C. § 346a(b)(2)(A)(i).

Under FIFRA, EPA regulates the sale, distribution, and use of pesticides through a licensing or registration program. Regulation of pesticides under FIFRA and the FFDCA is closely linked. Under FIFRA, EPA may not issue a registration for a pesticide use that has "unreasonable adverse effects on the

environment." *See* FIFRA section 3(c)(5) & (7), 7 U.S.C. § 136a(c)(5) & (7).

B. Protections for Subjects in Human Research

Human testing to determine the effects of therapeutic drugs and other chemicals, including pesticides, has been undertaken and the results submitted to the United States government for many years. To assure the protection of individuals participating in human testing that EPA conducts or supports, EPA implemented the "Common Rule" in 1991, codified at 40 C.F.R. Part 26.

In 2005, Congress passed Section 201 of the Department of the Interior, Environment and Related Agencies Appropriations Act for 2006, Public Law No. 109-54, § 201, 119 Stat. 499, 531 (the "Appropriations Act"), which addressed EPA's policies related to the use of human testing. Congress specified that none of the funds made available by the Appropriations Act may be used by EPA to "accept, consider or rely on third-party intentional dosing human toxicity studies for pesticides, or to conduct intentional dosing human toxicity studies for pesticides until the Administrator issues a final rulemaking on this subject." Congress further required that the final rulemaking "shall not permit the use of pregnant women, infants or children as subjects; [and] shall be consistent with the principles proposed in the 2004 report of the National Academy of Sciences on intentional human dosing and the principles of the Nuremberg Code with respect

to human experimentation . . . ." *Id.*

On February 6, 2006, EPA promulgated the Research Rule pursuant to the requirements, *inter alia*, of the Appropriations Act.

III. SCOPE OF REVIEW

The standard and scope of review applicable to judicial review of the Research Rule is found in the Administrative Procedure Act ("APA"), 5 U.S.C. § 706. Pursuant to the APA, this court reviews the Research Rule based on the record the agency presents to the reviewing court. *Florida Power & Light Co. v. Lorion*, 470 U.S. 729, 743-44 (1985); *National Audubon Soc'y v. Hoffman*, 132 F.3d 7, 14 (2d Cir. 1997). *See also* 5 U.S.C. § 706 (courts "shall review the whole record or those parts of it cited by a party"). When there is a contemporaneous explanation of the agency decision, the validity of that action "must stand or fall on the propriety of that finding, judged of course, by the appropriate standard of review," and thus "the focal point for judicial review should be the administrative record already in existence, not some new record made initially in the reviewing court." *Camp v. Pitts*, 411 U.S. 138, 142-143 (1973).

The record for judicial review in this case consists of "(1) the order involved; (2) any findings or report on which it is based; and (3) the pleadings, evidence, and other parts of the proceedings before the agency." Fed. R. App. P.

16(a). The agency is responsible for maintaining the documents received and prepared in connection with a rulemaking, and for certifying the administrative record. *Fund for Animals v. Williams*, 245 F. Supp. 2d 49, 56-57 (D.D.C. 2003). The record presented by the agency is entitled to a presumption of regularity; courts assume that the agency properly designated the record absent clear evidence to the contrary. *Citizens to Preserve Overton Park v. Volpe*, 401 U.S. 402, 415 (1971); *Bar MK Ranches v. Yuetter*, 994 F.2d 735, 740 (10th Cir. 1993).

IV. ARGUMENT

EPA properly did not include the five documents identified by Petitioners in the administrative record compiled for judicial review of the Research Rule. Documents A1, A2 and B were not considered by EPA in connection with the Research Rule. Documents B, C and D are deliberative, and therefore not part of the record courts use to review agency actions.

A. Documents Not Considered by EPA in Connection with the Research Rule are Not Properly Part of the Record.

The administrative record consists of those documents considered or relied upon by the agency in connection with its agency action. *See Bar MK Ranches*, 994 F.2d at 740. Documents A1, A2 and B do not fall within this category.

Documents A1 and A2 relate to EPA's instructions to staff about how to implement the Congressional prohibition on the use of human studies, not EPA's

interpretation of the Appropriations Act concerning the scope of the Research Rule. The Appropriations Act contained two distinct but related directives to EPA. First, it prohibited EPA from accepting, considering or relying on any third-party intentional dosing human toxicity study for pesticides prior to EPA promulgating a rule on this subject. Appropriations Act, Section 201. Second, it required EPA to promulgate a rule. *Id.* In response, EPA developed two parallel, yet separate tracks for addressing these two particular directives.

Documents A1 and A2 relate to the first of these two directives. Documents A1 and A2 provided internal, interim guidance to assist EPA staff in implementing the prohibition on the use of human studies while those prohibitions were in place. EPA's purpose in drafting this guidance was to assist staff in avoiding potential violations of the Appropriations Act while a rule was being promulgated; it was not developed to inform the Agency how to promulgate a rule, and EPA did not use it as such. Therefore, as reflected by EPA's certification of the revised record in this case, these documents were not considered by EPA in connection with the separate directive of the Appropriations Act to promulgate a rule addressing human testing.

The interpretation of statutory language from the Appropriations Act in the internal interim guidance documents does not convert Documents A1 and A2 into

documents considered by EPA in connection with the Research Rule. Documents A1 and A2 were prepared in order to ensure that any actions EPA staff took with regard to human testing would not inadvertently violate the provisions of the Appropriations Act. Therefore, the definitions used in the internal interim guidance were intentionally drafted in a broad manner so as to avoid noncompliance with any potential interpretation of the statutory language. The fact that these definitions were, in some instances, broader than those proposed in the proposed Research Rule and then subsequently adopted in the final Research Rule following EPA policy development and notice and comment proceedings does not make them part of the administrative record for the Research Rule. Contrary to Petitioners' arguments, they were not "evidence", "findings" or "proceedings" before EPA in the Research Rule rulemaking. *Cf.* Motion at 4.

Document B is unrelated to the Research Rule and was not considered by EPA in connection with the rulemaking. The document is entitled "DDVP (Draft 7/22/05: 12:00 PM)." The document is one of a number of chemical-specific fact sheets that EPA developed for chemicals for which it has received human studies. The document discusses the specific scientific and ethical aspects of submitted human studies and makes recommendations concerning whether to rely upon those studies in agency actions *specific to that chemical* (*e.g.*, establishing tolerance

levels). This document contains chemical-specific facts relevant to a risk assessment for DDVP. The eventual outcome of EPA's decision-making process for DDVP has no bearing on the Research Rule.

Petitioners incorrectly argue that EPA admits that it used Document B in preparation of the Research Rule. Motion at 4-5. Petitioners cite to EPA's statement that the document concerns "EPA's development of a policy related to whether, and how, to use human studies in Agency decisionmaking." *Id.* Petitioners incorrectly assume that the "policy" and "decisionmaking" relate to the Research Rule. However, as should be evident from the document, Document B concerns development of a policy for the use of particular studies in EPA decisionmaking related to agency action specific to DDVP. It is not a document that should be in the administrative record for the Research Rule.[1/]

B. Documents Reflecting Deliberative Process Are Not Part of the Administrative Record.

Judicial review of a decision by an administrative agency should be based on the reasons given by the agency and the information considered by the agency in the course of making the decision, not on the agency's internal decisionmaking

---

[1/] Evidence extrinsic to the administrative record may be considered by courts to determine a party's standing. Petitioners' contention that Document B is relevant to their standing argument provides no basis to add the document to the administrative record. Motion at 5 n. 5.

process. *See Motor Vehicle Mfrs. Ass'n v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983); *PLMRS Narrowband Corp. v. FCC*, 182 F.3d 995, 1001 (D.C. Cir. 1999). Courts have long respected the importance of excluding from judicial review information that reveals that deliberative process, *see United States v. Morgan*, 313 U.S. 409, 422 (1941), and have overwhelmingly recognized that documents which reflect the deliberative process are generally not part of the record on review.[2/] *See, e.g., Suffolk County v. Secretary of Interior*, 562 F.2d 1368, 1384 (2d Cir. 1977) ("review of deliberative memoranda reflecting an agency's mental process . . . is usually frowned upon"); *PLMRS Narrowband*, 182 F.3d at 1001 (videotape of agency meeting not part of record); *San Luis Obispo Mothers for Peace v. Nuclear Regulatory Comm'n*, 751 F.2d 1287, 1324-29 (D.C. Cir. 1984) (predecisional transcripts and related documents not part of record).

Whether ruling on deliberative documents in the context of a privilege or a disclosure issue, courts have recognized the importance of shielding deliberative materials from judicial scrutiny. In *Checkosky v. SEC*, 23 F.3d 452, 489 (D.C. Cir.

[2/] Deliberative documents are those that (1) make recommendations or express opinions on legal or policy matters, and (2) are prepared prior to a final decision in order to assist the agency decisionmaker in arriving at his or her decision. *Town of Norfolk v. United States Army Corps of Eng'rs*, 968 F.2d 1438, 1458 (1st Cir. 1992); *see Tigue v. United States Dept. Of Justice*, 312 F.3d 70, 76 (2d Cir. 2002).

1994), the petitioners sought discovery of, *inter alia*, internal agency documents including draft opinions and revisions to drafts, as well as minutes and notes of the agency meetings where drafts were discussed. The court held that the agency's deliberations were privileged from discovery and not subject to judicial review. *Id.* The court explained that agency decisions were like judicial opinions, in that both speak for themselves:

> "Just as a Judge cannot be subjected to such [questioning about how he reached his decisions], so the integrity of the administrative process must be equally respected." *In passing on final agency action, we therefore have refused to consider . . . documents recording the deliberative process leading to the agency's decision.*

Id. (emphasis added; internal quotations and citation omitted), citing *United States v. Morgan*, 313 U.S. at 422 (similarly drawing a comparison between judicial and administrative processes).

The rationale for excluding deliberative process materials from the record for judicial review remains valid even where those materials are publicly known or available (*i.e.*, not claimed as privileged). As the court in *San Luis Obispo* stated:

> Inclusion in the record of documents recounting deliberations of agency members is especially worrisome because of its potential for dampening candid and collegial exchange between members of multi-head agencies. While *public* disclosure stifles debate to some extent, *judicial* disclosure would suppress candor still further since off-hand remarks could turn out to have a *legal* significance they would not have if barred from the record on review.

751 F.2d at 1326 (emphasis in original); *see also Ohio Valley Envt'l Coalition v. Whitman*, No. 3:02-0059, 2003 WL 43377, at *6 (S.D. W. Va. Jan. 6, 2003) (refusing to consider as part of the administrative record deliberative documents obtained by plaintiffs and submitted to the court, including internal agency reports, memoranda, and e-mails); *Ad Hoc Metals Coalition v. Whitman*, 227 F. Supp. 2d. 134, 143 (D.D.C. 2002) (interagency review memoranda placed in public docket but excluded from administrative record).

When an agency has issued a formal opinion or written statement of its reasons for acting, deliberative process documents should not be used to impeach that decision. *Kansas State Network, Inc. v. FCC*, 720 F.2d 185, 191 (D.C. Cir. 1983) (rejecting addition to the record of a transcript of an open meeting of the agency). Citing the rule that deliberative documents are privileged and not subject to discovery, the court applied the same rationale to exclude publicly available deliberative documents from the record on review:

> Just as *disclosure* of predecisional documents would "injure the consultative process within the government," so too would *judicial review* of the agency's deliberations. In general, an agency's action should be reviewed based upon what it accomplishes and the agency's stated justifications.

Id. (emphasis added; citations omitted). *See also New Mexico v. EPA*, 114 F.3d 290, 295 (D.C. Cir. 1997) (declining to supplement the record with publicly

disclosed documents describing pre-decisional policy discussions between EPA and other agencies).[3/]

As illustrated by these cases, it would be inappropriate to include the obviously deliberative Documents B, C and D in the record in this petition for review. Document B contains the heading "DRAFT-CONFIDENTIAL-INTERNAL- DELIBERATIVE." As mentioned above, this draft document was prepared to inform and make recommendations to management about the DDVP risk assessment; it was never intended to reflect the final decision regarding the use of human studies for the DDVP risk assessment. Even if Document B had in some way been considered in connection with the Research Rule, it is, as its heading indicates, an internal, deliberative, draft document that is not properly included in an administrative record. *See San Luis Obispo*, 751 F.2d at 1326.

Document C is one EPA employee's internal staff comments on a draft version of the Research Rule prior to publication of the proposed rule for public comment. It purports to contain a recommendation from EPA's Office of

---

[3/] Courts have allowed supplementation of the record to include those portions of deliberative materials that contain new factual data or information. *See National Courier Ass'n v. Board of Governors of Fed. Reserve Sys.*, 516 F.2d 1229, 1242 (D.C. Cir. 1975); *New Mexico*, 114 F.3d at 295 (refusing to include deliberative materials that added no new data to the debate). However, the five documents identified by Petitioners do not contain new data considered in connection with the Research Rule.

Enforcement and Compliance Assurance ("OECA") to the office developing the Research Rule. However, this document is, at most, a draft recommendation; Ms. Love, the author, is not the OECA official authorized to send OECA's recommendation. Thus, this memorandum reflects only internal staff-level comments; such deliberative materials are not appropriately included in the administrative record.[4/]

Finally, the handwritten notes of Document D do not belong in the administrative record. Document D contains the notes of a mid-level manager who was briefed by staff on the status of the Research Rule. The notes identify issues related to the Research Rule, reflecting the deliberations within EPA that were ongoing at the time the briefing was conducted. The notes contain no data or evidence that would indicate the notes belong in the administrative record.

Petitioners incorrectly argue that the handwritten notes contain "evidence" of EPA knowledge of the laundering of a study. Motion at 6. The "evidence" Petitioners cite is a hypothetical presented to explain to the manager the concept of laundering a study. Declaration of William Jordan, ¶5, attached as Exhibit 1. EPA has no evidence that Monsanto "laundered" a study through the University

---

[4/] Even if Document C represented final OECA comments, it would still represent internal deliberative recommendations and comments and not be a part of the administrative record.

of Bangalore. *Id.* ¶ 4, 5. There would have been no reason to "launder" studies at the time these notes were taken because there were no restrictions prior to the Research Rule based upon the intent of the submitter of third-party studies to EPA. *Id.* ¶ 4. These deliberative documents should not be added to the administrative record.

CONCLUSION

For these reasons, the Court should deny Petitioners' motion to complete the administrative record.

Respectfully submitted,

SUE ELLEN WOOLDRIDGE
Assistant Attorney General
Environment and Natural Resources Division
U.S. Department of Justice

ALAN D. GREENBERG
Environmental Defense Section
U.S. Department of Justice
1961 Stout St. - 8th Floor
Denver, Colorado 80294
(303) 844-1366

OF COUNSEL:
Angela Huskey
U.S. Environmental Protection Agency
Washington, DC 20460

October 13, 2006

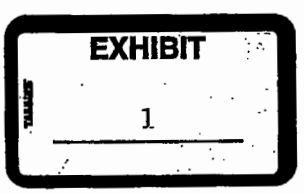
DECLARATION OF WILLIAM JORDAN IN SUPPORT OF EPA'S OPPOSITION TO PETITIONERS' MOTION TO COMPLETE THE ADMINISTRATIVE RECORD

I, William Jordan, declare:

1. I hold the position of Senior Policy Advisor for the Office of Pesticide Programs ("OPP"). I have been employed at the Environmental Protection Agency ("EPA" or "Agency") for over 30 years. Before serving as Senior Policy Advisor, I served in various senior positions in OPP. I am familiar with the rule titled "Protections for Subjects in Human Research" ("Research Rule") as I have been working on human studies issues since 2002. I served as the Agency's representative to the National Academy of Sciences ("NAS") on the contract that led to the NAS report, "Intentional Human Dosing Studies for EPA Regulatory Purposes," and was assigned to develop the proposed Research Rule before the Appropriations Act was enacted.

2. On September 20, 2005, John Carley, another EPA employee who also worked on the development of the Research Rule, and I met with Anne Lindsay, the Deputy Director for OPP, to brief her on the status of and issues related to the proposed Research Rule in preparation for Ms. Lindsay's participation in an internal conference of Agency staff being held with EPA Regions 8 and 10 on September 26-29, 2005. At one point during that meeting, we informed Ms. Lindsay of arguments that were being made by commenters about potential weaknesses of the "intent" provision of the proposed Research Rule.

3. The "intent" provision of the Research Rule basically says that the Research Rule requirements for third-party human research are applicable to research involving intentional exposure of human subjects if the person who conducted or



supported the research "intended . . . to submit results of the research to EPA for consideration in connection with any action that may be performed by EPA under the Federal Insecticide, Fungicide, and Rodenticide Act (7 U.S.C. 136 *et seq.*) or section 408 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 346a) . . . ."

4. EPA had been hearing from various commenters that this provision would give industry and pesticide manufacturers an incentive to "launder" studies through foreign universities or other establishments so that they could avoid the requirements of the Research Rule because EPA would be unable to prove that the researcher or sponsor had the requisite "intent." However, at the time of our September 20, 2005 meeting, EPA had no evidence before it that such "laundering" was, in fact, taking place. EPA had not received any studies from anyone that had been conducted in this way nor had any commenters submitted any evidence to the Agency documenting such a plan or practice. Moreover, it was highly unlikely that the Agency would have had any evidence of such "laundered" studies at the time Mr. Carley and I briefed Ms. Lindsay, as there had been no restrictions prior to the Research Rule based upon this "intent" element.

5. The reference in Ms. Lindsay's notes to this issue ("intent – Monsanto launders study thru Univ Bangalore") merely reflects an example of the hypothetical situations introduced by commenters to illustrate potential "loopholes" in EPA's proposed rule. Mr. Carley and I wanted to inform Ms. Lindsay of the concept of laundering a study, since we expected the issue to arise at the upcoming Agency meeting. The reference did not reflect any evidence in the Agency's possession that this practice was, in fact, occurring.

I declare under penalty of perjury that the foregoing is true and correct to the best of my knowledge, information, and belief.

Dated: Washington, District of Columbia
October 11, 2006

William Jordan

CERTIFICATE OF SERVICE

I hereby certify that on this 13th day of October 2006 I caused a true and correct copy of the foregoing Respondent EPA's Opposition to Petitioners' Motion to Complete Administrative Record to be deposited in the United States mail, first class, postage pre-paid, addressed to the following counsel of record:

Jan Hasselman
Patti Goldman
Earthjustice
705 Second Ave., Suite 203
Seattle, Washington 98104

Shelley Davis
Farmworker Justice Fund
1010 Vermont Ave., NW
Suite 915
Washington, DC 20005

Aaron Colangelo
Erik D. Olson
Natural Resources Defense Council
1200 New York Ave. NW, Suite 400
Washington, DC 20005

Michael E. Wall
Natural Resources Defense Council
111 Sutter Street, 20th Floor
San Francisco, CA 94104

ALAN D. GREENBERG
Environmental Defense Section
U.S. Department of Justice
1961 Stout Street - 8th Floor
Denver, Colorado 80294
(303) 844-1366